



6712-01

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 95

[ET Docket No. 08-59; FCC 14-124]

Medical Body Area Network

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document addresses an Order on Reconsideration and Second Report and Order in which the Commission takes further actions to foster the development and deployment of new and innovative Medical Body Area Network (MBAN) devices. In addressing petitions for reconsideration of the First Report and Order in this proceeding, the Commission provides MBAN users with additional flexibility to enable the implementation of technical standards being developed for MBAN devices, and clarify and modify portions of its rules to facilitate the coordination, deployment, and use of MBAN systems. In the Second Report and Order portion in this proceeding, the Commission finalizes the process for selecting a MBAN Coordinator. This coordinator will facilitate use of the MBAN frequencies, which operate in shared-use bands. Collectively, our actions will allow the development of new and innovative health care applications.

DATES: Effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, except for § 95.1225(c), which contains information collection requirements that have not been approved by the Office of Management and Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of § 95.1225(c).

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SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration and Second Report and Order, ET Docket No. 08-59, FCC 14-124, adopted August 20, 2014 and released August 21, 2014. 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 e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Summary of Order on Reconsideration

1. In the Order on Reconsideration and Second Report and Order, the Commission took further actions to foster the development and deployment of new and innovative Medical Body Area Network (MBAN) devices. MBAN technology provides a platform for the wireless networking of multiple body-worn sensors used for measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities. By addressing petitions for reconsideration of the First Report and Order in this proceeding, we provided MBAN users with additional flexibility to enable the implementation of technical standards being developed for MBAN devices, and clarified and modified portions of our rules to facilitate the coordination, deployment, and use of MBAN systems.

Authorized Locations

2. Health Care Facilities. The Commission revised § 95.1203 of its rules to limit use of the 2360-2390 MHz band to hospitals and other establishments that offer services, facilities and beds for use beyond a 24-hour period in rendering medical treatment. It eliminated a portion of the definition that included 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. By limiting the types (and, thus, the numbers) of medical institutions in the 2360-2390 MHz band, the Commission intended to make it easier for both the MBAN and AMT coordinators to establish, implement and enforce efficient and effective coordination procedures. Further, it found that limiting potential locations would simplify their efforts to identify and remedy any harmful interference in the extremely unlikely event it occurs.

3. Although GE Healthcare, Phillips Healthcare, and the Aerospace and Flight Test Radio Coordinating Council (AFTRCC) (the "Joint Parties") had suggested this approach as part of their comprehensive set of proposed rules, they had not discussed the rationale for this limitation until the filing of their Petition for Reconsideration. Because the Petition for Reconsideration stated with particularity the reasons why the Commission should adopt their proposed authorized locations definition, it found that the public interest would be served by taking the Joint Parties' facts and arguments into consideration.

4. As part of this decision, the Commission determined that, because the existing MBAN standard will support numerous patients in the 2390-2400 MHz band, and because frequency reuse techniques can augment that capacity in many situations, no health care facilities – including those that do not qualify for use of the 2360-2390 MHz band – will be precluded from operating MBAN systems. For this reason, the Commission disagreed with SmartEdgeNet that

health care providers will be “denied the benefits of MBAN” if the Commission limited the authorized locations as requested.

5. Antenna Locations. In their Petition for Reconsideration, the Joint Parties claimed that § 95.1213, titled “Antennas,” appeared to exclude the installation of outdoor antennas for the 2390-2400 MHz band at locations above a building’s first floor, such as balconies and roof terraces, and that this was not the intent of the rule. Upon reconsideration, the Commission agreed and expressly found that it was not necessary to apply antenna height restrictions – which were originally intended as a constraint on temporary outdoor use of MedRadio antennas regardless of the band in which the transmitter operated – to antennas used for MedRadio transmitters operating in the 2390-2400 MHz band.

6. The Commission concluded that, based on the permissible outdoor use in this band and the relatively low power operations of MBAN transmitters (which effectively limits any gain in coverage that is often associated with increased antenna height), there is no need to prescribe a specific antenna height limit (for either permanent or temporary outdoor antennas used for this band) and revised § 95.1213 as set forth in the rules.

MBAN Definition and Permissible Communications

7. MBAN Configurations with a Single Body-Worn Device. The Commission amended Appendix 1 to subpart E of part 95 (“Glossary of Terms”) to define an MBAN as a low power network consisting of a MedRadio programmer/control transmitter and one or more medical body-worn devices. The Commission found the argument of the Joint Parties that the pairing of a programmer/control transmitter with a single body-worn device “will likely be common” was plausible, concluding that there could be times where best treatment practices could require the use of only a single body-worn device.

8. Use of Bedside Devices. Under the Commission’s rules as adopted in the First Report and Order, a medical body-worn device is defined as an apparatus that is placed on or in close proximity to the human body (*e.g.*, within a few centimeters) for the purpose of performing diagnostic or therapeutic functions. The Commission clarified that bedside devices, which would require a physical attachment to the patient (e.g. by wire or tube), would meet the definition even though there are other parts of the apparatus that are located away from the body. The Commission further clarified that the “few centimeters” language in the rule should be read as a general example and not the codification of a specific distance requirement. Based on this clarification, the Commission did not grant the Joint Parties request to modify the rule to remove the “few centimeters” language.

9. Allowing Greater Flexibility in Designing MBAN Systems. Together § 95.1209(g) (“Permissible Communications”) and the MBAN definition contained in Appendix 1, subpart E of the part 95 Rules (“Glossary of Terms”) established the MedRadio programmer/control transmitter and the medical body-worn device as distinct elements that must be present in every MBAN; allow body-worn transmitters to relay information in the 2360-2400 MHz band only to a programmer/control transmitter that is part of the same MBAN; and prohibit a programmer/control transmitter from using the 2360-2400 MHz band to relay information to another programmer/control transmitter.

10. The Commission modified existing rule § 95.1209(g) to provide an exception to permit communications between programmer/control transmitters of different MBAN systems for the sole purpose of avoiding interference to each other, based on the text of the existing MedRadio rules for Medical Micropower Networks. It recognized that allowing MBAN systems in the 2360-2390 MHz band (as well as the 2390-2400 MHz band) to coordinate use among themselves of the available MBAN frequencies could promote efficient spectrum use. The Commission emphasized that it considered the modified requirement to be a limited exception to

the general rule and, in agreement with the Joint Parties, noted that programmer/control transmitters would continue to be barred from relaying the control message to each other. It retained the prohibition on programmer/control transmitters relaying other information (such as medical data) to each other.

11. The Commission amended § 95.1209 of the rules to eliminate the language that precludes body-worn devices from communicating with other body-worn devices in the 2360-2400 MHz band. It recognized that doing so could potentially enhance patient welfare by preserving battery life and enhancing signal strength in situations that may adversely affect the reception of data. Further, the Commission noted that the adoption of industry standards, it may have made it both feasible and practical to produce such equipment.

12. Additionally, the Joint Parties asked that the Commission allow either a programmer/control transmitter or a body-worn device to perform as a “coordinator node” in an MBAN system. According to the Joint Parties, coordinator node is the “...term used in IEEE 802.15.6 for the node responsible for coordinating the MAC function (e.g., assigning TDMA slots to other nodes) and being the main routing hub for communication with all other nodes in the MBAN star topology.” As an example, the Joint Parties described a scenario in which a body-worn device serves as a coordinator node to transmit information related to the technical operation of the network (e.g., what communication protocols to use) to other body-worn devices within the MBAN system and aggregate the patient data that it receives from other body-worn devices. Because the Commission decided to permit a body-worn device within an MBAN system to communicate with another body-worn device, it concluded that the Joint Parties would be able to design MBAN systems consistent with their request under the existing rules and that no rule modifications were necessary.

13. 2390-2400 MHz band. The Commission denied the Joint Parties’ request to eliminate all restrictions on MBAN systems that operate in the 2390-2400 MHz band. Such a

change would have allowed networks that consist of multiple programmer/control transmitters, networks that do not include any programmer/control transmitters, and networks in which different groups of programmer/control transmitters and body-worn devices communicate between and among each other. The Commission disagreed with the Joint Parties' assertion that the rationale for the MBAN system design requirements in § 95.1209(g) related exclusively to concerns in the 2360-2390 MHz band and applying the restriction to the 2390-2400 MHz band served no purpose. Instead, it noted that entities operating in the 2360-2390 MHz band may need to default to the 2390-2400 MHz band and found that it would be unwise to further complicate such transitions by allowing the band to be populated by medical devices operating under many different system designs. Nevertheless, the Commission did note that the First Report and Order left open the potential to revisit the permissible use restrictions after gaining further experience with MBAN operations and it deemed continuing this approach to be reasonable and appropriate to the circumstances.

Device Operation

14. In the First Report and Order, the Commission adopted transmission requirements for the component parts of an MBAN – the programmer/control transmitters and body-worn devices. The Commission applied much of the existing MedRadio rule on “Permissible Communications,” 47 CFR 95.1209, to MBAN operation. Among these requirements, § 95.1209(b), in pertinent part, addresses the operation of body-worn devices by stating that no MedRadio implant or body-worn transmitter shall transmit except in response to a transmission from a MedRadio programmer/control transmitter or in response to a non-radio frequency actuation signal generated by a device external to the body with respect to which the MedRadio implant or body-worn transmitter is used.

Additionally, with regard to programmer/control transmitters, § 95.628(c) states that 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.

15. The Joint Parties asserted that § 95.1209 as adopted in the First Report and Order permitted only a polled media access control (MAC) protocol – that is, that the only time a body-worn device can operate is immediately after the receipt of a transmission from the programmer/control transmitter. The Commission found that this assertion was based upon an overly narrow reading of the rule and was inconsistent with the language of the First Report and Order. It stated that while a polled access scenario would comply with the rules, other access modes are permissible provided that the body-worn devices operate in response to whatever instructions are transmitted by their associated programmer/control transmitter. The Commission thus determined that the rules allow sufficient flexibility to account for the Joint Parties’ concerns and made no changes to the rule.

16. The Commission modified § 95.628(c) of the rules, as shown below, to clearly state that body-worn transmitters must be capable of ceasing transmissions when necessary to avoid interference in the 2360-2390 MHz band. It agreed that it is “critical that all MBAN devices... cease operation in 2360-2390 MHz in the absence of a control message,” and noted that, because the rules adopted in the First Report and Order require a programmer/control transmitter operating in the 2360-2390 MHz that fails to receive a control message to cease operation and allow body-worn transmitters to transmit only in response to a transmission from the programmer/control transmitter, such a requirement was already implicit.

Coordination and Registration

17. Registration Requirement for the 2390-2400 MHz Band. In the First Report and

Order, the Commission adopted a registration requirement for the 2360-2390 MHz band to facilitate coordination with AMT operations in that band, but it did not adopt a registration requirement for the 2390-2400 MHz band. On reconsideration, the Commission amended its rules to require that entities preparing to use the 2390-2400 MHz band with equipment that is capable of also operating in the 2360-2390 MHz band and who are eligible to operate MBAN systems in the 2360-2390 MHz band register the MBAN system – regardless of whether they have any current intent to eventually use the 2360-2390 MHz band capacity of their equipment. The Commission agreed with ASHE that such a requirement will give the coordinator and health care facilities a more complete understanding of the current and potential local spectrum environment for MBANs and will allow qualifying health care facilities (and their equipment vendors and installers) to better plan their facilities with respect to appropriate efficient network architecture and systems planning and implementation. The Commission further noted that the modified registration requirement is more limited and less burdensome than a more comprehensive requirement that the Commission rejected in the First Report and Order, and concluded that the benefits of providing the MBAN coordinator with this important additional information outweigh the fairly slight increase in registration costs for the limited number of MBAN operators discussed.

18. Registration Requirement for the 2360-2390 MHz Band. In the First Report and Order, the Commission required all MBAN devices operating in the 2360-2390 MHz band to be registered with a frequency coordinator, and adopted § 95.1223 addressing MBAN registration and coordination. Upon reconsideration, the Commission agreed with the Joint Parties that the language in § 95.1223(a) that required registration of all MBAN devices a health care facility proposes to operate in the 2360-2390 MHz band was broader than necessary. It also noted that, while the introductory text in § 95.1223(a) suggests that all MBAN devices should be registered, the registration information specified in subparts (1) through (7) of the rule does not address

body-worn devices. Furthermore, subparts (3) and (5) specifically speak to “control transmitter[s]” (which we are updating to read “MedRadio programmer/control transmitter” to provide clarity and consistency). Because the existing rule construction may create confusion in that it could appear to be inconsistent or ambiguous, the Commission amended the introductory text of § 95.1223(a) as shown below. Under the revision, the Commission did not require that the MBAN user provide the coordinator with unique identifying data (e.g., a serial number) for each programmer/control transmitter. The Commission agreed with the Joint Parties that it will be sufficient to provide the quantity and type (i.e. equipment that may have different technical characteristics) of programmer/control transmitters at each MBAN installation. The Commission accomplished this objective by retaining the requirement in § 95.1223(a)(3) that programmer/control transmitter information include the manufacturer name, model number and FCC identification number. The practical effect of the revised rules is that health care facilities will be able to account for large groups of devices under a single filing.

19. Finally, the Commission clarified that replacement of programmer/control transmitters having the same technical characteristics as those reported on the health care facility's registration (i.e., the manufacturer name, model number and FCC identification number) will not trigger additional notification requirements under § 95.1223(b) of the rules.

20. Interaction between MBAN and AMT Coordinators. Under § 95.1225(b)(2) of the Commission's rules, the MBAN Coordinator is required to 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. Additionally, the MBAN coordinator must approve any changes made to an authorized MBAN installation before operation could begin with the altered parameters. Accordingly, § 95.1223(b) states, in pertinent part, that a health care facility must notify the MBAN coordinator of any material change to the MBAN's location or operating parameters, and that it may not operate under changed operating parameters until the

frequency coordinator determines whether such changes require coordination with the AMT coordinator. The Joint Parties had suggested edits to the coordinator duties listed in § 95.1225 of the rules. The Commission concluded that the Joint Parties' proposed edits to § 95.1225(b) were already addressed in § 95.1223(c) and concluded that it would be unnecessarily repetitive to make the requested edits.

21. The Commission determined that it would be beneficial to further clarify the procedures for how the AMT coordinator is consulted before an MBAN location or operation is changed. Specifically, the Commission found the need to provide clarification as to whether coordination with or notification to the AMT coordinator would be required if the modified MBAN facility would operate beyond line-of-sight of an AMT receive facility. It determined that the best course in such cases is to apply the existing procedures outlined in § 95.1223(c)(1), which requires the MBAN coordinator to approve operation without prior coordination with the AMT coordinator, but also requires the MBAN coordinator to notify the AMT coordinator and provide the AMT coordinator with the opportunity to concur that the MBAN facility is beyond line of sight. Accordingly, the Commission revised § 95.1223(b) of the rules to state that the MBAN coordinator must evaluate the proposed changes and comply with either (c)(1) or (c)(2), as appropriate, prior to authorizing a modified MBAN operation. Such a change satisfies the Joint Parties' request that the Commission clarify the advance consultation requirement for the AMT coordinator, and does so in a way that complements our existing rules for coordinating MBAN operations.

22. Notification of Interference. The Commission did not adopt a request by the Joint Parties to amend § 95.1223(a) of the rules to include a specific requirement that, if a health care facility or the MBAN coordinator is notified of MBAN interference to an AMT receive antenna, the MBAN user must cease transmissions on the frequencies causing interference. The Commission pointed out that § 95.1211(c) of the rules plainly states that MBAN devices may not

cause harmful interference to authorized stations operating in the 2360-2400 MHz band which places the onus of avoiding such interference squarely on the operator of these devices. Accordingly, it is the MBAN user's responsibility to respond to interference complaints, and to be prepared to cease operation as necessary to avoid causing harmful interference. The Commission also emphasized that failure to abide by this rule will subject an MBAN user to appropriate Commission enforcement action. The existing rules give the MBAN coordinator the responsibility to identify the MBAN that is the source of interference and the authority to notify the registered health care facility to cease operation as may be appropriate to the circumstances. Moreover, any health care facility planning to operate MBAN devices in the 2360-2390 MHz band will have provided to the MBAN coordinator, pursuant to the rules, a point of contact in the event the MBAN user is directed to cease operation. Thus, the Commission concluded that, together, the rule defining the MBAN user responsibilities and the rule describing the functions of the 2360-2390 MHz band MBAN coordinator should provide for the prompt identification and resolution of any harmful interference caused by an MBAN to AMT operations.

23. Testing of Installed MBAN Equipment. The Joint Parties and ASHE requested the Commission to require hospitals or equipment vendors to certify to the MBAN coordinator that testing of the relevant 2360-2390 MHz MBAN equipment was conducted in situ and confirmed that the equipment does not operate outdoors. The Commission found that its existing rules and processes are sufficient to address such concerns. It noted that all MBAN equipment capable of operating in the 2360-2390 MHz band is certified to be under the equipment authorization process to demonstrate compliance with the indoor operation restrictions and that, under the existing rules, MBAN users must acknowledge when registering with an MBAN coordinator the need to comply with these requirements. In this regard, the Commission noted that it has given MBAN coordinators broad discretion to implement coordination procedures to ensure that MBAN operations are permitted only when and where they will not interfere with AMT

operations. Thus, if an MBAN coordinator determines that the type of testing and certification the Joint Parties and ASHE seeks is warranted, it may ask a hospital or equipment vendor to provide such information as part of the coordination process.

Equipment Authorization

24. Attached Antennas and Operation in the 2360-2390 MHz Band. The Commission did not adopt the Joint Parties' request that § 95.1213 of the rules, which describes MBAN antenna placement, be modified "to clarify that an antenna must be permanently affixed to its MBAN transmitter" for devices operating in the 2360-2390 MHz portion of the band. The Commission determined that there was little risk that MBAN users will make post-market device modifications, noting that it was not aware of any issues with unauthorized modification of the existing base of MedRadio devices, nor had the Joint Parties provided any supporting evidence that this is a common occurrence that would support additional rules tailored to MBAN operation in the 2360-2390 MHz band. It also found that the existing rules already protect against the potential harm described by the Joint Parties. Specifically, § 95.639(f)(5) of the rules states that the antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization.

25. Equipment Labeling Requirement. The labeling requirement for MBAN devices states that MedRadio programmer/control transmitters operating in the 2360-2400 MHz band shall be labeled as provided in part 2 of the 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.

26. The Commission denied the Joint Parties' request that, in the event that the warning is not included on the device label, the Commission should require that the warning be placed on the front page of the instruction manual in capital letters. On reconsideration, the Commission found that the Joint Parties had not offered any reason for it to question this analysis the Commission undertook in the First Report and Order, or to convince it that additional steps were needed to ensure that "all personnel are fully aware" of the status of MBAN devices.

27. Publication of Equipment Authorization Requirements. The Joint Parties asked that the Commission take steps to ensure that the requirements for equipment authorization of MBAN devices be "clear for all to follow." They did not propose any specific rule modifications, but instead submitted a list of "expected attestation and certification requirements for MBAN equipment. While the Commission declined to codify the Joint Parties' specific requirements, it indicated that it will draw on existing resources (for example, the OET Laboratory Division's Knowledge Database (KDB)) and staff will continue to be available to ensure that information regarding authorization procedures for MBAN equipment is published in a readily accessible manner, and that MBAN equipment is authorized in compliance with Commission rules.

SECOND REPORT AND ORDER

28. The Commission's rules require that MBAN operations in the 2360-2390 MHz be registered and coordinated to ensure that AMT operations in this band are protected from harmful interference. The registration and coordination functions are to be performed by a frequency coordinator to be designated by the Commission. An MBAN coordinator will be required to maintain a database of MBAN registrations that includes the locations of MBAN systems that operate in the 2360-2390 MHz band, determine when MBAN transmitters are within line-of-sight of AMT receive facilities, coordinate MBAN operations with the coordinator for AMT services, notify registered MBAN users when they must change frequencies or cease operations consistent with a coordination agreement between the MBAN and AMT coordinator, and develop

procedures to ensure that MBAN users operate consistent with the coordination requirements.

29. In the Second Report and Order, the Commission determined that it will select only one MBAN coordinator for a ten-year term. After the ten-year term, the coordinator will serve until either it elects not to continue as coordinator or is removed by the Commission. The MBAN coordinator may rely on a third-party consultant for technical services necessary to fulfill its responsibilities, but will be required to disclose information about the technical qualifications of the third-party consultant and the contractual arrangement it has with the consultant. The MBAN coordinator will be required to provide service on a non-discriminatory basis to all eligible health care institutions and will be permitted to charge reasonable fees that reflect only its actual costs (including the costs associated with coordination, such as the AMT coordinator's cost and the expense of any third-party technical consultant). The Wireless Telecommunications Bureau (Bureau), acting under delegated authority as provided in the Commission's rules, will select the MBAN coordinator. The Bureau will execute a Memorandum of Understanding (MOU) with the selected coordinator, which will describe the duties and responsibilities of the coordinator and provide for removal of the coordinator if circumstances warrant. These requirements are described in further detail in the following paragraphs.

30. Single Coordinator. The Commission found it appropriate to select only one MBAN coordinator at this time given the characteristics of the MBAN service. The health care community represents a small part of the radiofrequency user ecosystem and the number of MBAN registrants is likely to be proportionally small. A single coordinator will simplify MBAN registration for health care institutions because there will be a single point of contact and the registration process will be analogous to the Wireless Medical Telemetry Service (WMTS) registration process that is familiar to many entities in this specialized group, and will make coordination with AMT coordinator simpler. The Commission noted that the authority already delegated to the Bureau to certify frequency coordinators for the services it administers allows it

to introduce competitive coordination into a service with an exclusive coordinator, and noted that the Bureau will consider, in the future, whether to certify one or more additional coordinators if it determines that such an action would serve the public interest.

31. Term of Service. The Commission required that the MBAN coordinator agree to serve a ten-year term. After the initial ten-year term, the MBAN coordinator will continue to serve until the coordinator acts to vacate the role or the Commission acts to remove the coordinator under the procedures discussed. The Commission also adopted the proposal in the Further Notice to require that the MBAN coordinator transfer the MBAN registration data to another entity designated by the Commission if the coordinator cannot or chooses not to continue as coordinator. The Commission directed the Bureau to incorporate this requirement into the MOU that it will execute with the MBAN coordinator. As part of the MOU, the Bureau should also address what notice the MBAN coordinator must give the Commission to provide adequate time to select a replacement coordinator, in the event that the coordinator intends to vacate the coordinator role. This notice will have to provide sufficient time for the Bureau to select a replacement coordinator, for the replacement coordinator to establish a registration and coordination system, and for the incumbent MBAN coordinator to transfer the registration data to the replacement coordinator. The Commission also recognized that it is possible that the coordinator would not continue in its role at some point. In such a case, these notice and transfer requirements will be necessary to ensure an effective transition of coordinators. The provisions will help avoid having a period of time during which there would be no functioning MBAN registration and coordination regime or creating a re-registration burden on MBAN licensees.

32. Because the role of the MBAN coordinator is essential to prevent harmful interference to a primary service, the Commission indicated that it is important to allow the MBAN coordinator to be replaced by the Commission if necessary. Consistent with the existing procedures for the WMTS coordinator, the Commission delegated to the Bureau the authority to

remove the MBAN coordinator after giving adequate notice if it determines that such an action would serve the public interest. The Bureau can include specific provisions in the MOU, including the notice it will give the coordinator.

33. Qualifying Criteria. In the Further Notice, the Commission sought comment on the minimum qualifying criteria that should be established for selecting an MBAN coordinator and proposed that parties interested in being designated an MBAN coordinator must, at a minimum, demonstrate that they meet the following criteria:

- Ability to register and maintain a database of MBAN transmitter locations and operational parameters;
- Knowledge of or experience with medical wireless systems in health care facilities (e.g., WMTS);
- Knowledge of or experience with AMT operations;
- Ability to calculate and measure interference potential between MBAN and AMT operations and to enter into mutually satisfactory coordination agreements with the AMT coordinator based on the requirements in § 95.1223(c);
- Ability to develop procedures to ensure that registered health care facilities operate an MBAN consistent with the requirements in § 95.1223.

34. In the Second Report and Order, the Commission required applicants applying to become the MBAN coordinator to demonstrate that they meet these five criteria. It determined that these criteria “ensure that the designated coordinator can successfully accomplish the functions required by our rules.” The Commission declined to add the additional criteria suggested by ASHE and Philips/GE to the core criteria that it adopted, noting that some of these elements are already addressed by the five criteria it adopted and determining that other elements of the proposed criteria described qualities that would likely be useful for an MBAN coordinator

to possess but did not appear essential for performing the coordination obligations required by the rules that it adopted, were insufficiently concrete to warrant certification, or would be expected to attend compliance with the criteria it has specified.

35. The Commission also found that the MBAN coordinator should be able to rely on a contract with a third party for technical expertise, and it will consider such arrangements as part of a candidate's demonstration that it satisfies the core qualifying criteria. The Commission recognized that it may be difficult to identify a single entity that satisfies all the minimum qualifying criteria that it has adopted, and stated that a candidate that lacks expertise in the core criteria may choose to rely on a third party for technical support to demonstrate that it would be able to provide all of the MBAN registration and coordination functions with minimal delay. The Commission noted that the Bureau may exercise its authority to terminate the tenure of the MBAN coordinator if the third-party technical consultant stops providing service to the MBAN coordinator and the Bureau is not persuaded that either the MBAN coordinator can perform these necessary duties without assistance of a third-party consultant or use of a replacement consultant will allow the coordinator to meet its obligations under our rules.

36. The Commission found that MBAN coordinator candidates that rely on third party contracts to demonstrate compliance with the core qualifying criteria will need to disclose certain information about such contracts. The Commission found that demonstration of the core qualifying criteria will require the disclosure of more detailed information because the relationship between the MBAN coordinator and a third-party technical expert will affect both the coordinator's ability to carry out its responsibilities and the program's ability to continue if either the coordinator or the third-party expert must relinquish its role. The Commission therefore directed the Bureau to require that applicants for the MBAN coordinator role relying on a third party consultant make a number of attestations regarding the consultant and the contract between the consultant and the applicant, and to take this information into account when judging the

suitability of applicants for the MBAN coordinator position. This information must include the identity and qualifications of any third-party technical consultant the MBAN coordinator will rely on, the length of time that the contract between the MBAN coordinator and the third-party consultant would be in effect, and under what circumstances that contract could terminate.

37. The Commission also indicated that the MOU should also recognize the possibility that the technical consultant would stop providing service to the MBAN coordinator. Upon such an occurrence, the MBAN coordinator would need time to employ a replacement consultant who meets the Commission's high standards and, if such a coordinator is not found, the Commission needs time to replace the MBAN coordinator. The Commission provided the Bureau with the discretion to include such requirements in the MOU it executes with the MBAN coordinator.

38. Fees for Service. The Commission decided to permit the MBAN coordinator to set fees for MBAN registration and coordination (as opposed to having the Commission or the Bureau prescribe fees. The Commission required that the fees charged for MBAN registration and coordination be reasonable and reflect only the MBAN coordinator's actual costs of providing the coordination and registration functions. The MBAN coordinator will be required to provide the coordination and registration functions on a not-for-profit basis. The Commission determined that requiring that the MBAN coordinator provide services on a not-for-profit basis was necessary because, with likely only one MBAN coordinator, it cannot rely on competitive market forces to serve as a check on the fees associated with MBAN registration and coordination. If competitive forces are introduced and more than one coordinator is selected, however, the Commission recognized that the need for such regulations may no longer exist and may need to be reconsidered. The Commission also required that the MBAN coordinator must provide services on a non-discriminatory basis to all eligible health care institutions.

39. The Commission concluded that the MBAN coordinator should establish MBAN user fees that include all costs associated with MBAN registration and coordination, including the

cost of any third-party technical consultant employed by the MBAN coordinator and the fees of the AMT coordinator. This approach establishes a single pay point for MBAN users and will simplify the registration and coordination process for them, and is supported by the record. As with the other costs for which the MBAN user is responsible, the cost of any third-party technical consultant must be reasonable. This cost can include only the MBAN coordinator's actual costs for such consultation services. The amount of the payment to the AMT coordinator should be determined by agreement between the AMT and MBAN coordinators, and would be incorporated into the overall coordination fee that an MBAN user incurs. The Commission indicated that it expects the AMT coordinator to pass on only its actual coordination costs, on a not-for-profit basis, to the MBAN coordinator. This cost may include the actual cost to the AMT coordinator of coordinating Federal AMT operations, but may not include charges for work performed by Federal employees such as the Federal Government Area Frequency Coordinators. Because the costs incurred by the AMT coordinator will be charged to the MBAN user as part of the registration and coordination fees paid to the MBAN coordinator, the Commission found that there is no need to place a requirement in our rules that the MBAN user bear direct responsibility for the AMT coordinator's cost.

40. On the matter of how reasonable costs should be evaluated and what oversight the Commission should exercise over AMT-MBAN coordination fees, the Commission observed that the Bureau has the authority to investigate the reasonableness of the MBAN registration and coordination fees, and it will do so as appropriate, either in response to complaints or on its own motion. The MBAN coordinator will be required to provide the Bureau with any information it requests in the course of conducting such an investigation. In judging the reasonableness of MBAN registration and coordination fees the Bureau should consider the customary practices in other bands where registration or coordination is required under the Commission's rules. The Commission also required the MBAN coordinator to provide the Bureau with its fee schedule

upon request. This fee notification requirement coupled with the ability to investigate the reasonableness of fees will provide a necessary incentive for the MBAN and AMT coordinators to maintain the fee structure for MBAN registration and coordination at a reasonable level.

41. MBAN Coordinator Selection. The Commission directed the Bureau, acting under its existing delegated authority, to select the MBAN coordinator. Because the procedures the Bureau used in selecting the WMTS coordinator were successful, it directed it to employ a similar process to select the MBAN coordinator, including releasing a Public Notice to announce procedures for interested parties to submit applications for consideration as an MBAN coordinator, issuing an Order to designate the MBAN coordinator, and executing a MOU on behalf of the Commission with the selected coordinator that will set forth the coordinator's authority and responsibilities. The Commission anticipated that the MBAN coordinator would assume its duties upon the execution of this MOU.

42. The Commission agreed with Philips/GE that the MBAN coordinator and AMT coordinator should quickly reach agreement on mutually agreeable procedures to create coordination agreements. Until such procedures are in place, no registered MBAN system can be deployed. Hence, the Commission required the selected MBAN coordinator to report to the Commission when it has procedures in place with the AMT coordinator allowing coordination agreements for MBAN systems to be made. If no such report is made within six months of selection of the MBAN coordinator, the Commission directed the Bureau to take all necessary action to promote such an agreement.

43. The Commission declined to adopt AFTRCC's suggestion that selection of the MBAN coordinator be contingent on executing a coordination agreement with AFTRCC. The Commission emphasized that it is the responsibility of both the selected MBAN coordinator and AFTRCC to cooperate in good faith in developing procedures for MBAN coordination.

44. Petition for Rulemaking. Ben Bartlett, who identifies himself as a law student at the

University of California Hastings College of Law, filed a Petition for Rulemaking requesting that the Commission allocate spectrum for MBAN use in an unused portion of the television frequency bands. Bartlett claimed that the 2360-2400 MHz band is unsuitable for MBAN use because interference between MBAN systems and the AMT and amateur services would put patients at risk and interfere with the operation of these services, that the amount of spectrum available for MBAN operations was not sufficient to meet the future demand for medical applications, and that the current MBAN frequencies have limited propagation characteristics compared to the TV bands. He envisioned an expanded role for MBAN devices where patients will not be tied to a hub because the wireless link will be able to traverse long distances and pass through buildings and other obstacles.

45. The Commission concluded that the petition does not warrant further consideration at this time and dismissed it without prejudice. First, the Commission pointed out that MBAN systems are designed to provide wireless monitoring of patients over short distances to provide patients with mobility in hospitals and other health care facilities. In the First Report and Order, the Commission concluded that the 2360-2400 MHz band is well suited for this purpose given the ability of MBAN devices to share with spectrum with the incumbent users. Nothing in the petition gave the Commission reason to question this conclusion. Second, the petition asserted that the amount of spectrum the Commission has allocated for MBAN use would not be sufficient to meet future demand. The Commission found this claim to be speculative at best, particularly given that no MBAN devices have been deployed. Finally, the petition did not provide the technical details necessary to draw conclusions as to the feasibility of the long-range medical wireless devices that Bartlett envisions. The Commission concluded that deployment of these types of devices may be possible under its existing rules in other frequency bands.

PROCEDURAL MATTERS

46. Final Regulatory Flexibility Certification. The Regulatory Flexibility Act of 1980, as

amended (RFA)¹ requires that a regulatory flexibility analysis be prepared for rulemaking proceedings, unless the agency certifies that "the rule will not have a significant economic impact on a substantial number of small entities."² The RFA generally defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."³ In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.⁴ A small business concern is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).⁵

47. In the Order on Reconsideration and Second Report and Order, the Commission addressed a number of issues related to designating the MBAN coordinator for the 2360-2390 MHz band. Among other actions, the Commission concludes to only designate one MBAN coordinator, but delegates to the Wireless Telecommunication Bureau (Bureau) the authority to possibly designate more than one coordinator at a later date. The Commission adopts a number of qualifying criteria to guide the Bureau in selecting the coordinator, such as the ability to register and maintain a database of MBAN transmitter locations, knowledge of wireless systems in healthcare facilities and of AMT operations, and the ability to calculate and measure interference potential between MBAN and AMT operations. The Commission also adopts a rule requiring that the MBAN coordinator provide registration and coordination to all eligible healthcare facilities on a non-discriminatory basis, provide the registration and coordination services on a not-for-profit basis, notify the Commission six months prior to ceasing to perform

¹ The RFA, *see* section 5 U.S.C. S 601 *et. seq.*, has been amended by the Contract With America Advancement Act of 1996, Pub. L. 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

² 5 U.S.C. 605(b).

³ 5 U.S.C. 601(6).

⁴ 5 U.S.C. 601(3) (incorporating by reference the definition of "small business concern" in Small Business Act, 15 U.S.C. S 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."

⁵ Small Business Act, section 15 U.S.C. S 632.

the functions of frequency coordinator, and transmit the MBAN registration data in a usable form to another coordinator designated by the Commission if it ceases to be the frequency coordinator. While the decisions made and rules adopted in the Order on Reconsideration and Second Report and Order could have a significant economic impact on the MBAN coordinator, the Commission has decided to designate only one MBAN coordinator. Although the Commission does allow the Bureau to possibly designate multiple coordinators at a later date, it does not foresee there ever being more than a couple of MBAN coordinators.

48. The Commission also addresses several issues related to MBAN users. First, the revisions to the authorized location rule will not increase the number of health care facilities that can use the 2360-2390 MHz band, and therefore will not impose regulatory burdens on any new small entities. Second, in the Report and Order, the Commission originally declined to require registration for the 2390-2400 MHz band users because it concluded that such a requirement “would unnecessarily burden hospitals that do not need assistance from the MBAN coordination.” Under the revised registration requirement we are adopting, the scope is narrower and it targets only those hospitals that may eventually need to interact with MBAN coordinator. We find that the benefit of providing the MBAN coordinator with this additional information outweighs the slight increase in registration costs for this limited number of MBAN operators. In addition, we find that the increase in registration costs is minor, and therefore will not have a significant economic impact on a substantial number of small entities. Lastly, the remaining revisions to § 95.1223 do not change the regulatory burden on small business health care facilities; they merely clarify the rules and do not have a significant economic impact on any new small entities.

49. Therefore, the Commission certifies that the requirements of this Order on Reconsideration and Second Report and Order will not have a significant economic impact on a substantial number of small entities. The Commission will send a copy of the Order on

Reconsideration and Second Report and Order including a copy of this final certification, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, see 5 U.S.C. 801(a)(1)(A). In addition, the Order on Reconsideration and Second Report and Order and this certification will be sent to the Chief Counsel for Advocacy of the Small Business Administration, and will be published in the Federal Register. See 5 U.S.C. 605(b).

50. Congressional Review Act. The Commission will send a copy of this Order on Reconsideration and Second Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

51. Paperwork Reduction Act. This document contains new and modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. The requirements will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. The Commission will publish a separate notice in the Federal Register inviting comment on the revised information collection requirements adopted in this document. The requirements will not go into effect until OMB has approved them and the Commission has published a notice announcing the effective date of the information collection requirements.

ORDERING CLAUSES

52. 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. 154(i), 301, 302a, 303(e), 303(f), 303(r), and 307(e), this Order on Reconsideration and Second Report and Order IS ADOPTED.

53. The rules and requirements adopted herein will become effective **[30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, except for 47 CFR 95.1225(c), which includes new or modified information collection requirements that require approval by Office of Management and Budget under the PRA and WILL BECOME

EFFECTIVE after such approval, on the effective date specified in a notice that the Commission publishes in the Federal Register announcing such approval and effective date.

54. Pursuant to the authority of section 5(c) of the Communications Act of 1934, as amended, 47 U.S.C. 155(c), the Commission delegate authority to the Wireless Telecommunications Bureau as set forth in this Second Report and Order.

55. The Petition for Rulemaking filed by Ben Bartlett in ET Docket Nos. 08-59 and 04-186 is DENIED.

56. The Joint Petition for Reconsideration of GE Healthcare, Phillips Healthcare, and the Aerospace and the Flight Test Radio Coordinating Council is GRANTED IN PART and DENIED IN PART.

57. The Petition for Reconsideration of The American Society for Healthcare Engineering of the American Hospital Association is GRANTED.

58. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this Order on Reconsideration and Second Report and Order, including the Final Regulatory Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 95

Communications equipment, Medical devices, Reporting and recordkeeping requirements.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch,
Secretary.

Final Rules

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

PART 95 – PERSONAL RADIO SERVICES

1. The authority citation for part 95 is revised to read as follows:

Authority: 47 U.S.C. 154, 301, 302(a), 303, and 307(e).

Subpart E – Technical Regulations

2. Section 95.628 is amended by revising paragraph (c) 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.

* * * * *

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

* * * * *

3. Appendix 1 to Subpart E is amended by revising the definition of “Medical Body Network” to read as follows:

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 one or more 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)**

4. 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. For the purposes of this subpart, health care facilities are limited to hospitals and other establishments, both Federal and non-Federal, that offer services, facilities and beds for use beyond a 24 hour period in rendering medical treatment.

5. Section 95.1209 is amended by revising paragraph (g) to read as follows:

§ 95.1209 Permissible communications.

* * * * *

(g) Medical body-worn transmitters may relay only information in the 2360-2400 MHz band to a MedRadio programmer/control transmitter or another medical body-worn transmitter device 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 other MedRadio programmer/controller transmitters. Wireless retransmission of all other information from an MBAN transmitter 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.

Notwithstanding the above restriction, a MedRadio programmer/control transmitter in the 2360-2400 MHz band may communicate with another MedRadio programmer/control transmitter in the 2360-2400 MHz band to coordinate transmissions so as to avoid interference between the two Medical Body Area Networks.

* * * * *

6. Section 95.1213 is revised to read as follows:

§ 95.1213 Antennas.

(a) An antenna for a MedRadio transmitter shall not be configured for permanent outdoor use.

(b) 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.

(c) Paragraphs (a) and (b) of this section do not apply to MedRadio operations in the 2390-2400 MHz band.

7. Section 95.1223 is amended by revising the section heading, paragraph (a) introductory text, and paragraphs (a)(3), (a)(5), and (b) to read as follows:

§ 95.1223 Registration and frequency coordination.

(a) Registration. Prior to operating MBAN devices that are capable of operation in the 2360-2390 MHz band, a health care facility, as defined by § 95.1203, must register with a frequency coordinator designated under § 95.1225. Operation of MBAN 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:

* * * * *

(3) Number of MedRadio programmer/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;

* * * * *

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

* * * * *

(b) Notification. A health care facility shall notify the frequency coordinator whenever an MBAN programmer/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 and locations as those reported on the health care facility's registration which will cover the replacement transmitter(s). A health care facility shall keep the information contained in each registration current and shall notify the frequency coordinator of any material change to the MBAN's location or operating parameters. In the event that the health care facility proposes to change the MBAN's location or operating parameters, the MBAN coordinator must first evaluate the proposed changes and comply with paragraph (c) of this section, as appropriate, before the health care facility may operate the MBAN in the 2360-2390 MHz band under changed operating parameters.

* * * * *

8. Section 95.1225 is amended by revising paragraphs (a) and (b)(1) and adding paragraph (c) 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 by eligible health care facilities.

(b) ***

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

* * * * *

(c) The frequency coordinator shall:

(1) Provide registration and coordination of MBAN operations to all eligible health care facilities on a non-discriminatory basis;

(2) Provide MBAN registration and coordination services on a not-for-profit basis;

(3) Notify the Commission of its intent to no longer serve as frequency coordinator six months prior to ceasing to perform these functions; and

(4) Transfer the MBAN registration data in usable form to a frequency coordinator designated by the Commission if it ceases to be the frequency coordinator.