



Federal Communications Commission
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Small Entity Compliance Guide

Medical Body Area Networks

Order on Reconsideration and
Second Report and Order
FCC 14-124
ET Docket No. 08-59
Released: August 20, 2014

This Guide is prepared in accordance with the requirements of Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It is intended to help small entities—small businesses, small organizations (non-profits), and small governmental jurisdictions—comply with the new rules adopted in the above-referenced FCC rulemaking docket(s). This Guide is not intended to replace the rules and, therefore, final authority rests solely with the rules. Although we have attempted to cover all parts of the rules that might be especially important to small entities, the coverage may not be exhaustive. This Guide may, perhaps, not apply in a particular situation based upon the circumstances, and the FCC retains the discretion to adopt approaches on a case-by-case basis that may differ from this Guide, where appropriate. Any decisions regarding a particular small entity will be based on the statute and regulations.

In any civil or administrative action against a small entity for a violation of rules, the content of the Small Entity Compliance Guide may be considered as evidence of the reasonableness or appropriateness of proposed fines, penalties or damages. Interested parties are free to file comments regarding this Guide and the appropriateness of its application to a particular situation; the FCC will consider whether the recommendations or interpretations in the Guide are appropriate in that situation. The FCC may decide to revise this Guide without public notice to reflect changes in the FCC's approach to implementing a rule, or to clarify or update the text of the Guide. Direct your comments and recommendations, or calls for further assistance, to the FCC's Consumer Center:

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Medical Body Area Networks

1. Objectives of the Proceeding

Medical body area networks, or MBANs for short, are networks of devices worn on the human body that communicate with a programmer/controller device unattached to the body using a wireless communication link. MBANs are 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. In the *First Report and Order (MBAN Order)* adopted May 24, 2012 in ET Docket 08-59, the Commission amended the Part 95 rules governing MedRadio devices to allow MBANs to operate in the 2360-2400 MHz frequency band on a secondary basis.

The *Order on Reconsideration (MBAN Reconsideration Order)* adopted on August 20, 2014 in ET Docket 08-59 responded to Petitions for Reconsideration filed by: the American Society for Healthcare Engineering of the American Hospital Association (ASHE) on October 10, 2012; and GE Healthcare, Phillips Healthcare, and the Aerospace and Flight Test Radio Coordinating Council (AFTRCC) (Joint Parties) jointly filed on October 11, 2012. The petitioners sought amendment or clarification on a variety of issues related to eligibility, technical requirements, and coordination.

The *Second Report and Order (Second MBAN Order)* in ET Docket 08-59 was also adopted on August 20, 2014. This order finalized the criteria and selection process for the designation of an MBAN coordinator.

A copy of this *Order on Reconsideration and Second Report and Order* is available at: https://apps.fcc.gov/edocs_public/attachmatch/FCC-14-124A1_Rcd.pdf

2. Rules that the Commission Amended

In the *MBAN Reconsideration Order* the Commission granted several of the petitioners' requests to modify the rules adopted in the initial *MBAN Order*. Specifically, it narrowed the MBAN user eligibility in the 2360-2390 MHz band to health care facilities that offer services, facilities and beds for use beyond a 24 hour period; required such health care facilities to register their MBAN systems that are capable of operating across the 2360-2400 MHz band with the MBAN coordinator; and eliminated location restrictions for antennas that transmit in the 2390-2400 MHz band. Additionally, regarding the MBAN operating requirements, the Commission modified the MBAN definition to permit single device networks; specified that all MBAN devices must shut down when their associated MedRadio programmer/controller shuts down; allowed MedRadio programmer/controllers used in separate MBAN systems to communicate directly for the sole purpose of avoiding interference with each other; and it modified certain restrictions on intra-MBAN communications. Finally, the Commission clarified which devices must be registered with an MBAN coordinator and it further defined the interaction between the AMT and MBAN coordinators.

In the *Second MBAN Order*, the Commission finalized several decisions related to the MBAN coordination process. The Commission decided to select a single MBAN coordinator to serve an initial 10-year term and thereafter serve on an indefinite basis. The MBAN coordinator is required to give a 6-month notice before vacating the coordinator role and be required to transfer the MBAN registration data upon vacating. Applicants to be MBAN coordinator will be required to demonstrate that they meet a set of qualifying criteria including the ability to register and maintain a database of MBAN locations,

knowledge of or experience with medical wireless systems in health care facilities, knowledge of Aeronautical mobile telemetry (AMT) operations, and the ability to calculate and measure interference potential between MBAN and AMT operations. The MBAN coordinator may rely on a third-party technical consultant to satisfy the qualifying criteria. The Commission directed the Wireless Telecommunications Bureau (WTB) to select the MBAN coordinator by and then execute a Memorandum of Understanding with the coordinator setting forth the coordinator's authority and responsibilities. Finally, while the MBAN coordinator will be able to set the fees for MBAN registration and coordination, the Commission item specified that the services must be provided on a not-for-profit basis because competition will not otherwise serve as a check on the fees in a single-coordinator environment.

3. Definitions

MBANs are defined in the Part 95 rules as follows:

A low power network consisting of a MedRadio programmer/control transmitter and one or more 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.¹

4. Restrictions on MBAN Operation²

Use of MBANs must comply with the following restrictions:

- MBANs can be used only for diagnostic and therapeutic purposes.
- MBANs must be provided to a patient only under the direction of a duly authorized health care professional.
- MBANs may not cause harmful interference to other authorized stations operating in the 2360-2400 MHz band.
- MBANs must accept interference from other authorized stations operating in the 2360-2400 MHz band.
- MBAN devices may not be used to relay information to other devices that are not part of the MBAN using the 2360-2400 MHz frequency band except as follows: 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 MBANs.
- In order to protect AMT operations, there are additional restrictions placed on MBAN operation in the 2360-2390 MHz band: operation within this band may only occur indoors at an authorized healthcare facility (in this case, 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); and operation may only occur upon completion of registration, and, if necessary, coordination with an authorized MBAN frequency coordinator.
- MBAN transmitters must be certificated in accordance with Part 2 of the Commission's rules. To obtain certification, the manufacturer must submit a certification application as directed in

¹ See 47 C.F.R. Part 95, Subpart E, Appendix 1.

² See 47 C.F.R. §§ 95.603, 95.628, 95.1201, 95.1203, 95.1209, 95.1211, and 95.1223.

Subpart J of Part 2 of the Commission's rules. See <http://www.fcc.gov/encyclopedia/equipment-authorization-procedures> for more information.

- MBAN devices are licensed by rule and, as such, individual licenses are not required for MBAN use.

5. Technical Requirements³

MBANs must comply with a number of technical requirements designed to allow them to share the 2360-2400 MHz frequency band with primary users and other MBANs. Specifically, these requirements are that:

- An MBAN 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, an MBAN 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.
- All MBAN devices must cease operations if communications with their associated MedRadio programmer/controller is lost.
- MBAN transmitters are allowed a maximum emission bandwidth of 5 megahertz.
- MBAN transmitters operating in the 2360-2390 MHz band are allowed a maximum EIRP over the frequency bands of operation that shall not exceed the lesser of 1 mW or $10 \cdot \log(B)$ dBm, where B is the 20 dB emission bandwidth in MHz.
- MBAN transmitters operating in the 2390-2400 MHz band are allowed a maximum EIRP over the frequency bands of operation that shall not exceed the lesser of 20 mW or $16 + 10 \cdot \log(B)$ dBm, where B is the 20 dB emission bandwidth in MHz.
- In the first 2.5 megahertz beyond the 2360-2400 MHz band, 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. In addition, emissions from an MBAN transmitter that are more than 2.5 megahertz beyond any of the frequency bands authorized for MBAN operation must be less than field strength limits specified in the Part 95 rules.
- Each MBAN transmitter must maintain a frequency stability of ± 100 ppm of the operating frequency over the range 0 °C to 55 °C.

6. Labeling and Other Requirements⁴

MBANs must comply with a number of other requirements designed to inform medical professionals about the secondary status of MBANs and allow the Commission to enforce the Part 95 rules governing MBAN operation:

- All MBAN devices must be made available for inspection upon request by an authorized FCC representative.
- Persons operating body-worn MBAN transmitters are required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference.
- A disclosure statement as specified in the Part 95 rules must be included with each MBAN transmitting device. This disclosure statement warns that the device must accept interference

³ See 47 C.F.R. §§ 95.628, 95.633-639.

⁴ See 47 C.F.R. §§ 95.1207, 95.1215, and 95.1217.

from and not cause interference to primary users sharing the same frequency bands. The statement also warns that there is no guarantee that the MBAN device will not receive interference.

- MBAN programmer/control transmitters must be labeled with a statement as specified in the Part 95 rules. The statement warns that the device may not cause interference to and must accept interference from devices that are operating on a primary basis in the same frequency bands as the MBAN programmer/control transmitter. The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.
- MBAN programmer/controller transmitters must be identified by a serial number that is assigned by the device manufacturer. This serial number may be placed either on the device or in the instruction manual for the transmitter.

7. MBAN Coordinator⁵

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

- 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 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.
- Provide registration and coordination of MBAN operations to all eligible health care facilities on a non-discriminatory basis;
- Provide MBAN registration and coordination services on a not-for-profit basis;
- Notify the Commission of its intent to no longer serve as frequency coordinator six months prior to ceasing to perform these functions and transfer the MBAN registration data in usable form to a frequency coordinator designated by the Commission upon ceasing to be the frequency coordinator.

8. Weblink and Citations

The *Order on Reconsideration and Second Report and Order* adopted August 20, 2014: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 08-59, *First Report and Order and Further Notice of Proposed Rulemaking*, 29 FCC Rcd 10662 (2014). Available at: https://apps.fcc.gov/edocs_public/attachmatch/FCC-14-124A1_Rcd.pdf.

The *First Report and Order* adopted May 24, 2012: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 08-59, *First Report and Order and Further Notice of Proposed Rulemaking*, 27 FCC Rcd 6422 (2012). Available at:

⁵ See 47 C.F.R 95.1223 and 95.1225.

http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-12-54A1_Rcd.pdf

The *Notice of Proposed Rulemaking* that preceded the May 24, 2012 *First Report and Order: 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*, 24 FCC Rcd 9589 (2009). Available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-09-57A1_Rcd.pdf.

A previous small business compliance guide addressing the initial adoption of MBAN rules within the MedRadio service rules is available at: https://apps.fcc.gov/edocs_public/attachmatch/DA-13-1081A1_Rcd.pdf.