of 3 meters using measuring instrumentation with a CISPR quasi-peak detector.

(b) Unwanted emissions on frequencies above 960 MHz must not exceed 500 μV/m, measured at a distance of 3 meters using measuring equipment with an averaging detector and a 1 MHz measurement bandwidth.

§§ 95.2381–95.2383 [Reserved]

§ 95.2385 WMTS RF exposure evaluation.

Mobile and portable devices as defined in §§2.1091(b) and 2.1093(b) of this chapter operating in the WMTS are subject to radio frequency radiation exposure requirements as specified in §§1.1307(b), 2.1091, and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of WMTS devices must contain a statement confirming compliance with these requirements. Technical information showing the basis for this statement must be submitted to the Commission upon request.

[85 FR 18151, Apr. 1, 2020]

§§ 95.2387–95.2391 [Reserved]

§ 95.2393 WMTS labeling requirements.

Each WMTS device must be labeled with the following statement: ''Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.''

§ 95.2395 WMTS disclosure.

Manufacturers, installers and users of WMTS equipment are cautioned that the operation of this equipment could result in harmful interference to other nearby medical devices.

§§ 95.2397–95.2499 [Reserved]

Subpart I—Medical Device Radio Communications Service

§ 95.2501 Scope.

This subpart contains rules that apply only to the Medical Device Radio Communications (MedRadio) Service.

§ 95.2503 Definitions, MedRadio.

Duly authorized health care professional. A physician or other individual authorized under State or Federal law to provide health care services.

Medical Body Area Network (MBAN). An MBAN is 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-directional or uni-directional electromagnetic signals

Medical body-worn device. 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.

Medical body-worn transmitter. A MedRadio transmitter intended to be placed on or in close proximity to the human body (*e.g.*, within a few centimeters) used to facilitate communications with other medical communications devices for purposes of delivering medical therapy to a patient or collecting medical diagnostic information from a patient.

Medical Device Radio Communications (MedRadio) Service. An ultra-low power radio service for the transmission of non-voice data for the purpose of facilitating diagnostic and/or therapeutic functions involving implanted and body-worn medical devices.

Medical implant device. Apparatus that is placed inside the human body for the purpose of performing diagnostic or therapeutic functions.

Medical implant event. An occurrence or the lack of an occurrence recognized by a medical implant device, or a duly authorized health care professional, that requires the transmission of data from a medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted.

Medical implant transmitter. A MedRadio transmitter in which both the antenna and transmitter device are designed to operate within a human

body for the purpose if facilitating communications from a medical implant device.

Medical Micropower Network (MMN). An ultra-low power wideband network consisting of a MedRadio programmer/control transmitter and medical implant transmitters, all of which transmit or receive non-voice data or related device control commands for the purpose of facilitating functional electric stimulation, a technique using electric currents to activate and monitor nerves and muscles.

MedRadio channel. Any continuous segment of spectrum that is equal to the MedRadio emission bandwidth of the device with the largest bandwidth that is to participate in a MedRadio communications session.

MedRadio communications session. A collection of transmissions, that may or may not be continuous, between MedRadio system devices.

MedRadio emission bandwidth. The difference in frequency between the nearest points on either side of the carrier center frequency where the emission power is at least 20 dB below the maximum level of the modulated carrier power, measured using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1% of the emission bandwidth.

MedRadio equivalent isotropically radiated power (M–EIRP). Antenna input power times gain for free-space or intissue measurement configurations required for MedRadio equipment, expressed in Watts, where the gain is referenced to an isotropic radiator.

MedRadio programmer/control transmitter. A MedRadio transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver, or for triggering a transmitter, connected to a medical implant device or to a medical body-worn device used in the MedRadio Service; and which also typically includes a frequency monitoring system that initiates a MedRadio communications session.

§ 95.2505 MedRadio operator eligibility.

Only the following persons are eligible to operate transmitters in the MedRadio Service:

(a) Duly authorized health care professionals are permitted to operate MedRadio transmitters.

(b) Individuals may also operate MedRadio transmitters that they use at the direction of a duly authorized health care professional. This includes medical devices that have been implanted in or placed on the body of the individual by, or under the direction of, a duly authorized health care professional.

(c) Manufacturers of medical devices that include MedRadio transmitters, and their representatives, are eligible to operate MedRadio transmitters for the purpose of demonstrating such equipment to duly authorized health care professionals.

§ 95.2507 MBAN devices restricted to indoor operation within a health care facility.

Use of Medical Body Area Network (MBAN) devices in the 2360–2390 MHz band is restricted to indoor operation within a health care facility registered with the MBAN frequency coordinator under § 95.2509. 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.

§ 95.2509 MBAN registration and frequency coordination.

Operation of Medical Body Area Network (MBAN) devices is subject to the frequency coordination procedures in this section.

(a) The FCC will designate a frequency coordinator(s) to manage the operation of medical body area networks by eligible health care facilities.

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

(1) Register health care facilities that operate MBAN transmitters, maintain a database of these MBAN transmitter locations and operational parameters, and provide the FCC with

information contained in the database upon request;

(2) Determine if an MBAN is within line-of-sight of an Aeronautical Mobile Telemetry (AMT) receive facility in the 2360–2390 MHz band and coordinate MBAN operations with the designated AMT frequency 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 AMT frequency coordinators;

(4) Develop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements under this section; 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.

(c) *Registration.* Prior to operating MBAN devices that are capable of operation in the 2360–2390 MHz band, a health care facility must register with a frequency coordinator designated under § 95.2509. 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 (e) 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) Equivalent isotropically radiated power;

(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 number(s) and FCC identification number(s);

(4) Legal name of the health care facility;

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

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

(7) In the event that an MBAN has to cease operating in all or a portion of the 2360–2390 MHz band due to interference under § 95.2525 or changes in coordination under paragraph (e) 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 address, 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.

(d) *Notification.* A health care facility shall notify the MBAN 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 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 MBAN 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 (e) of this section as appropriate before the health care facility may operate the MBAN in the 2360–2390 MHz band under changed operating parameters.

(e) *Coordination procedures.* The MBAN 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 below.