(4) MedRadio devices operating with a total emission bandwidth not exceeding 300 kHz, centered at 403.65 MHz, provided that the transmit power is not greater than 100 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.01%, based on the total transmission time during a one-hour interval and a maximum of 10 transmissions per hour.

(c) *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.

(d) *Frequency monitoring in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands.* 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 same antenna used by the programmer/control transmitter for a communications session.

(1) 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.

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

(3) 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 authorized frequency band.

(e) *System shutdown.* 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 authorized alternate 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. This requirement does not apply to MedRadio operations in the 401–406 MHz band.

(f) *Requirements for MBAN 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.

§ 95.2561 MedRadio transmitter certification.

(a) Except as provided § 95.2535, each MedRadio transmitter (a transmitter that operates or is intended to operate as a station in the MedRadio Service) must be certified in accordance with this subpart and part 2 of this chapter.

(b) A grant of equipment certification for the MedRadio Service will not be issued for any MedRadio transmitter type that fails to comply with all of the applicable rules in this subpart.

§ 95.2563 MedRadio frequency bands.

MedRadio transmitters operate in the 401–406 MHz, 413–419 MHz, 426–432 MHz, 438–444 MHz, 451–457 MHz, and 2360–2400 MHz bands. The FCC does not

specify a channeling scheme for MedRadio systems.

(a) MedRadio transmitters associated with medical implant devices, which incorporate a frequency monitoring system as set forth in § 95.2559(a), may transmit on any frequency in the 401–406 MHz band.

(b) MedRadio transmitters associated with medical implant devices, which do not incorporate a frequency monitoring system as set forth in § 95.2559(a), may transmit on any frequency in the 401–402 MHz or 405–406 MHz bands, or on the frequency 403.65 MHz in the 402–405 MHz band.

(c) MedRadio transmitters associated with medical body-worn devices, regardless of whether a frequency monitoring system as set forth in § 95.2559(a) is employed, may transmit on any frequency in the 401–402 MHz or 405–406 MHz bands.

(d) MedRadio transmitters that are used externally to evaluate the efficacy of a more permanent medical implant device, regardless of whether a frequency monitoring system as set forth in § 95.2559(a) is employed, may operate on any frequency in the 402–405 MHz band, provided that:

(1) Such external body-worn operation is limited solely to evaluating with a patient the efficacy of a fully implanted permanent medical device that is intended to replace the temporary body-worn device;

(2) RF transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary due to unforeseen circumstances;

(3) The maximum output power of the temporary body-worn device must not exceed 200 nW EIRP; and

(4) The temporary body-worn device must comply fully with all other MedRadio rules applicable to medical implant device operation in the 402–405 MHz band.

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

(f) Only MedRadio transmitters that are part of a Medical Body Area Network (MBAN) may operate in the 2360–2400 MHz band.

§ 95.2565 MedRadio frequency accuracy.

Each MedRadio transmitter type must be designed to maintain a frequency stability of ±100 ppm of the operating frequency over the applicable temperature range set forth in this section. Frequency stability testing shall be performed over the appropriate temperature range.

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

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

§ 95.2567 MedRadio radiated power limits.

Each MedRadio transmitter type must be designed such that the MedRadio equivalent isotropically radiated power (M–EIRP) does not exceed the limits in this section. Compliance with these limits must be determined as set forth in § 95.2569.

(a) *Transmitters subject to frequency monitoring—401–406 MHz.* For MedRadio transmitters that are not excepted under § 95.2559(b) from the frequency monitoring requirements of § 95.2559(a):

(1) The M–EIRP within any 300 kHz bandwidth within the 402–405 MHz band must not exceed 25 microwatts.

(2) The M–EIRP within any 100 kHz bandwidth within the 401–402 MHz or 405–406 MHz bands must not exceed 25 microwatts.

(b) *Transmitters excepted from frequency monitoring—401–402 MHz and 405–406 MHz.* For MedRadio transmitters that are excepted under § 95.2559(b)(2) or (3) from the frequency monitoring requirements of § 95.2559(a):

(1) The M–EIRP of any transmitter operating in the 401–401.85 MHz or 405–406 MHz bands must not exceed 250 nanowatts in any 100 kHz bandwidth.