§ 95.1019 Marketing limitations.

Transmitters intended for operation in the LPRS may be marketed and sold only for those uses described in §95.1009.

[64 FR 69933, Dec. 15, 1999]

Subpart H—Wireless Medical Telemetry Service (WMTS)

SOURCE: 65 FR 44008, July 17, 2000, unless otherwise noted.

GENERAL PROVISIONS

§ 95.1101 Scope.

This part sets out the regulations governing the operation of Wireless Medical Telemetry Devices in the 608–614 MHz, 1395–1400 MHz and 1427–1429.5 MHz frequency bands.

[67 FR 6193, Feb. 11, 2002]

§ 95.1103 Definitions.

(a) Authorized health care provider. A physician or other individual authorized under state or federal law to provide health care services, or any other health care facility operated by or employing individuals authorized under state or federal law to provide health care services, or any trained technician operating under the supervision and control of an individual or health care facility authorized under state or federal law to provide health care services.

(b) Health care facility. A health care facility includes hospitals and other establishments that offer services, facilities and beds for use beyond a 24 hour period in rendering medical treatment, and institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including government entities and agencies such as Veterans Administration hospitals; except the term health care facility does not include an ambulance or other moving vehicle.

(c) Wireless medical telemetry. The measurement and recording of physiological parameters and other patient-related information via radiated bi-or unidirectional electromagnetic signals in the 608–614 MHz, 1395–1400 MHz, and 1427–1429.5 MHz frequency bands.

[65 FR 44008, July 17, 2000, as amended at 67 FR 6194, Feb. 11, 2002]

§ 95.1105 Eligibility.

Authorized health care providers are authorized by rule to operate transmitters in the Wireless Medical Telemetry Service without an individual license issued by the Commission provided the coordination requirements in §95.1111 have been met. Manufacturers of wireless medical telemetry devices and their representatives are authorized to operated wireless medical telemetry transmitters in this service solely for the purpose of demonstrating such equipment to, or installing and maintaining such equipment for, duly authorized health care providers. No entity that is a foreign government or which is active in the capacity as a representative of a foreign government is eligible to operate a WMTS transmitter.

§ 95.1107 Authorized locations.

The operation of a wireless medical telemetry transmitter under this part is authorized anywhere within a health care facility provided the facility is located anywhere a CB station operation is permitted under §95.405. This authority does not extend to mobile vehicles, such as ambulances, even if those vehicles are associated with a health care facility.

§ 95.1109 Equipment authorization requirement.

(a) Wireless medical telemetry devices operating under this part must be authorized under the certification procedure prior to marketing or use in accordance with the provisions of part 2, subpart J of this chapter.

(b) Each device shall 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.

§ 95.1111 Frequency coordination.

(a) Prior to operation, authorized health care providers who desire to use wireless medical telemetry devices
must register all devices with a designated frequency coordinator. The registration must include the following information:

1. Specific frequencies or frequency range(s) used;
2. Modulation scheme used (including occupied bandwidth);
3. Effective radiated power;
4. Number of transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers);
5. Legal name of the authorized health care provider;
6. Location of transmitter (coordinates, street address, building);
7. Point of contact for the authorized health care provider (name, title, office, phone number, fax number, e-mail address).

§ 95.1113 Frequency coordinator.

(a) The Commission will designate a frequency coordinator(s) to manage the usage of the frequency bands for the operation of medical telemetry devices.

(b) The frequency coordinator shall:

1. Review and process coordination requests submitted by authorized health care providers as required in §95.1111;
2. Maintain a database of WMTS use;
3. Notify users of potential conflicts;
5. Notify licensees—who are operating in accordance with §90.259(b)—of the need to comply with the field strength limit of §90.259(b)(11) prior to initial activation of WMTS equipment in the 1427–1432 MHz band.

§ 95.1115 General technical requirements.

(a) Field strength limits. (1) In the 608–614 MHz band, the maximum allowable field strength is 200 mV/m, as measured at a distance of 3 meters, using measuring instrumentation with a CISPR quasi-peak detector.

(2) In the 1395–1400 MHz and 1427–1429.5 MHz bands, the maximum allowable field strength is 740 mV/m, as measured at a distance of 3 meters, using measuring equipment with an averaging detector and a 1 MHz measurement bandwidth.

(b) Undesired emissions. (1) Out-of-band emissions below 960 MHz are limited to 200 µV/m, as measured at a distance of 3 meters, using measuring instrumentation with a CISPR quasi-peak detector.

(2) Out-of-band emissions above 960 MHz are limited to 500 µV/m as measured at a distance of 3 meters using measuring equipment with a CISPR quasi-peak detector.

(c) Emission types. A wireless medical telemetry device may transmit any emission type appropriate for communications in this service, except for video and voice. Waveforms such as electrocardiograms (ECGs) are not considered video.

(d) Channel use. (1) In the 1395–1400 MHz and 1427–1429.5 MHz bands, no specific channels are specified. Wireless medical telemetry devices may operate on any channel within the bands authorized for wireless medical telemetry use in this part.

(2) In the 608–614 MHz band, wireless medical telemetry devices utilizing broadband technologies such as spread spectrum shall be capable of operating within one or more of the following...
§ 95.1117 Types of communications.

(a) All types of communications except voice and video are permitted, on both a unidirectional and bidirectional basis, provided that all such communications are related to the provision of medical care. Waveforms such as electrocardiograms (ECGs) are not considered video.

(b) Operations that comply with the requirements of this part may be conducted under manual or automatic control, and on a continuous basis.

§ 95.1119 Specific requirements for wireless medical telemetry devices operating in the 608–614 MHz band.

For a wireless medical telemetry device operating within the frequency range 608–614 MHz and that will be located near the radio astronomy observatories listed below, operation is not permitted until a WMTS frequency coordinator specified in §95.1113 has coordinated with, and obtain the written concurrence of, the director of the affected radio astronomy observatory before the equipment can be installed or operated.

(a) Within 80 kilometers of:

1) National Astronomy and Ionosphere Center, Arecibo, Puerto Rico: 18°20'38.28" North Latitude, 66°45'09.42" West Longitude.

2) National Radio Astronomy Observatory, Socorro, New Mexico: 34°04'43" North Latitude, 107°37'04" West Longitude.

3) National Radio Astronomy Observatory, Green Bank, West Virginia: 38°26'08" North Latitude, 79°49'42" West Longitude.

(b) Within 32 kilometers of the National Radio Astronomy Observatory centered on:

<table>
<thead>
<tr>
<th>Very long baseline array stations</th>
<th>Latitude (north)</th>
<th>Longitude (west)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pie Town, NM</td>
<td>34°18'</td>
<td>109°07'</td>
</tr>
<tr>
<td>Kitt Peak, AZ</td>
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<td>111°57'</td>
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<tr>
<td>Los Alamos, NM</td>
<td>35°47'</td>
<td>106°15'</td>
</tr>
<tr>
<td>Fort Davis, TX</td>
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<td>North Liberty, IA</td>
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<td>Bremer, WA</td>
<td>48°08'</td>
<td>119°41'</td>
</tr>
<tr>
<td>Owens Valley, CA</td>
<td>37°14'</td>
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<td>Mauna Kea, HI</td>
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<tr>
<td>Hancock, NH</td>
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<td>71°59'</td>
</tr>
</tbody>
</table>


§ 95.1121 Specific requirements for wireless medical telemetry devices operating in the 1395–1400 MHz and 1427–1429.5 MHz bands.

Due to the critical nature of communications transmitted under this part, the frequency coordinator in consultation with the National Telecommunications and Information Administration shall determine whether there are any Federal Government systems whose operations could affect, or could be affected by, proposed wireless medical telemetry operations in the 1395–1400 MHz and 1427–1429.5 MHz bands. The locations of government systems

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in these bands are specified in footnotes US351 and US352 of §2.106 of this chapter.

[67 FR 6194, Feb. 11, 2002]

§ 95.1123 Protection of medical equipment.

The 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.

§ 95.1125 RF safety.

Portable devices as defined in §2.1093(b) of this chapter operating in the WMTS are subject to radio frequency radiation exposure requirements as specified in §§1.1307(b) and 2.1093 of this chapter. 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.

§ 95.1127 Station identification.

A WMTS station is not required to transmit a station identification announcement.

§ 95.1129 Station inspection.

All WMTS transmitters must be available for inspection upon request by an authorized FCC representative.

Subpart I—Medical Implant Communications (MICS)

Source: 64 FR 69933, Dec. 15, 1999, unless otherwise noted.

§ 95.1201 Eligibility.

Operation in the MICS is permitted by rule and without an individual license issued by the FCC. A person is permitted to operate medical implant transmitters connected to medical implant devices that have been implanted in that person by a duly authorized health care professional and medical implant programmer/control transmitters associated with their medical implant transmitter(s). Duly authorized health care professionals are permitted by rule to operate MICS transmitters. Manufacturers of medical implant devices and MICS transmitters and their representatives are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MICS transmitter. The term “duly authorized health care professional” means a physician or other individual authorized under state or federal law to provide health care services using medical implant devices. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

§ 95.1203 Authorized locations.

MICS operation is authorized anywhere CB station operation is authorized under §95.405.

§ 95.1205 Station identification.

A MICS station is not required to transmit a station identification announcement.

§ 95.1207 Station inspection.

All non-implanted MICS apparatus must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted medical implant transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

§ 95.1209 Permissible communications.

(a) Except for the purposes of testing and for demonstrations to health care professionals, medical implant programmer/control transmitters may transmit only operational, diagnostic and therapeutic information associated with a medical implant device that has been implanted by a duly authorized health care professional.

(b) Except in response to a medical implant event, no medical implant transmitter shall transmit except in response to a transmission from a medical implant programmer/control transmitter or a non-radio frequency actuation signal generated by a device...