Federal Communications Commission
Washington, D.C. 20554

May 19, 2011

**DA 11-912**

# Small Entity Compliance Guide

## Medical Device Radiocommunication Service

Memorandum Opinion and Order
FCC 10-128
ET Docket No. 06-135, RM-11271
Released: July 26, 2010

**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:**

**1-888-CALL-FCC (1-888-225-5322)**
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## 1. Objectives of the Proceeding

The Memorandum Opinion and Order responded to a Petition for Reconsideration submitted by Medtronic, Inc. on June 15, 2009. It grants reconsideration to the extent of including a provision in the MedRadio rules that permits the submission of transmitter output power measurements made using average power instrumentation techniques. It also makes several minor corrections or clarifications of an editorial nature with respect to other provisions. It denies reconsideration in all other respects.

The need for and objectives of the amended rules adopted in this Memorandum Opinion and Order are the same as those discussed in the 2009 Report and Order (*MedRadio Order)*. In the *MedRadio Order*, the Commission found that additional spectrum was required for the operation of advanced medical devices using wireless telecommunication technologies. Thus, building upon the legacy Medical Implant Communications Service (MICS), the Commission adopted service and technical rules for a new MedRadio Service that replicated, and expanded upon, many of the former MICS requirements. For example, the legacy MICS rules limited operation to implanted medical devices. However, the rules for the new MedRadio Service adopted in the *MedRadio Order* accommodated body-worn as well as implanted medical devices. Under this framework, the rules for MedRadio service incorporates the MICS 'core' band at 402-405 MHz – which continues to be limited to implanted devices; and also includes two megahertz of newly designated spectrum in the adjacent 'wing' bands at 401-402 MHz and 405-406 MHz – in which both body-worn and implanted devices are permitted. As with the MICS, the MedRadio service is housed within Part 95 of the Commission's rules. As a result, the legacy MICS and new MedRadio rules share many of the same licensing and technical requirements. Altogether, the MedRadio service provides a total of five megahertz of contiguous spectrum for advanced wireless medical radiocommunication devices serving a diverse range of diagnostic and therapeutic purposes in humans.

## 2. Rules that the Commission Amended

The Commission granted reconsideration of the 2009 *MedRadio Order* to the extent of amending the MedRadio rules to permit the submission of average power transmitter measurements. This action relates to a decision the Commission made in the *MedRadio Order* to consolidate the transmitter compliance measurement provisions formerly set forth in MICS rule Section 95.639 by creating a new rule Section 95.628(g)(3). The new rule deviated from the old rule in that it specified that power measurements be made using only peak power techniques. At the time it adopted the new rule, the Commission also deleted the reference in the old rule to certain measurement techniques set forth in an obsolete ANSI standard – as well as a reference to an alternative technique using a "peak detector function" over a period of time. The Commission subsequently recognized that removing the reference to the specific standard and the particular power measurement technique may have created uncertainty whether a previously acceptable average power measurement technique would continue to be allowed. In the *Memorandum Opinion and Order*, the Commission stated that it was not its intent to change the underlying frame of reference for measuring allowable transmit power, which is a maximum EIRP over a specified bandwidth.

By revising § 95.628(g)(3) of the Rules, the Commission made it clear that the submission of average power transmitter measurements continues to be an acceptable means of complying with technical rules relating to transmitter compliance. The Commission offers additional guidance on this matter in "FCC Guidance for Measuring the Output Power of Transmitting Devices Operating within the Medical Device Radiocommunication Service," Pub. No. 771134, at https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?switch=P&id=44167

The Memorandum Opinion and Order made editorial corrections or clarifications to several provisions concerning the frequency monitoring criteria and permissible communications for "listen-before-talk" (LBT) and non-LBT devices. These modifications served to make existing procedures easier to understand (by, for example, modifying the text of rules to reflect limits on the number of transmissions per hour for non-LBT devices), but they did not change the objectives for, or methods for complying with the underlying requirements. Thus, the compliance information provided for the *MedRadio Order* was not affected by these actions.

Finally, the Memorandum Opinion and Order denied reconsideration in all other respects and otherwise affirmed certain provisions of the MedRadio rules questioned by Medtronic.

*Memorandum Opinion and Order* available at http://fjallfoss.fcc.gov/edocs_public/attachmatch/FCC-10-128A1.doc (FCC Rcd 10414 (2010), 75 FR 52472, August 26, 2010.

*Report and Order* available at http://fjallfoss.fcc.gov/edocs_public/attachmatch/FCC-09-23A1.pdf (24 FCC Rcd 3474 (2009)).

**3. General Information**.

The new MedRadio service at 401-406 MHz will be governed under Part 95 of the Commission's rules, thus providing for license-by-rule operation throughout the 5 megahertz band. This approach minimizes regulatory procedures and will facilitate the more expeditious deployment of new generations of beneficial wireless medical devices in these bands that can improve the quality of life for countless Americans, thus serving the public interest, convenience and necessity. Furthermore, the operation of medical devices in the MedRadio band will be on a secondary, non-interference basis with respect to other authorized services and as such they must accept harmful interference from the systems operating in those services. MedRadio devices will operate on a shared, non-exclusive basis with respect to each other.

**4. Definitions.**

*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.

**5. Eligibility requirements for operation.**

Operation in the MedRadio service is permitted by rule and without an individual license issued by the FCC. Duly authorized health care professionals are permitted to operate MedRadio transmitters. Persons may also operate MedRadio transmitters to the extent the transmitters are incorporated into implanted or body-worn medical devices that are used by the person at the direction of a duly authorized health care professional. This includes medical devices that have been implanted in that person or placed on the body of that person by or under the direction of a duly authorized health care professional. Manufacturers of medical devices that include MedRadio 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 MedRadio 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. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

**6. Certification requirements.**

Each Medical Device Radiocommunication Service (MedRadio) transmitter (a transmitter that operates or is intended to operate in the MedRadio service) must be certified, except for such transmitters that are not marketed for use in the United States, but which otherwise comply with the MedRadio Service technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad. See 47 CFR § 95.603.

**7. Certification procedures.**

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, 218-219 MHz Service, LPRS, MURS, or MedRadio Service following the procedures in 47 CFR §2.907 and 47 CFR § 95.605.

**8. Recordkeeping and other Compliance Requirements**.

The Commission is using the licensing approach for the entire 401-406 MHz MedRadio band that is identical to that used for the existing MICS band at 402-405 MHz. Thus, rather than require individual transmitter licensing, the Commission authorizes operation by rule within the Citizens Band (CB) Radio Service under Part 95 of its Rules and pursuant to Section 307(e) of the Communications Act. To be authorized under Part 95, the transmitter must comply with applicable technical standards and other operating rules. The Commission concluded that this approach is beneficial because it minimizes the administrative burden on prospective licensees as compared with an individual licensing scheme. The Memorandum Opinion and Order does not change any of the reporting, recordkeeping, or other compliance requirements resulting from the rules adopted in the *MedRadio Order*.

**9. Where can I find documents about the Medical Radio Service proceeding.**

Investigation of the Spectrum Requirements for Advanced Medical Technologies,
ET Docket Nos. 06-135, 05-213, 03-92, RM-11271.

Memorandum Opinion and Order – adopted 7/15/10; released 7/26/10
http://fjallfoss.fcc.gov/edocs_public/attachmatch/FCC-10-128A1.pdf (25 FCC Rcd 10414 (2010).

Report and Order – adopted 3/19/09; released 3/20/09 http://fjallfoss.fcc.gov/edocs_public/attachmatch/FCC-09-23A1.pdf (24 FCC Rcd 3474 (2009)).

Notice of Proposed Rulemaking and Notice of Inquiry – adopted 7/13/06; released 7/18/06
http://fjallfoss.fcc.gov/edocs_public/attachmatch/FCC-06-103A1.pdf (21 FCC Rcd 8164 (2006)).