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## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 95

[ET Docket No. 06-135; FCC 10-128]

#### Spectrum Requirements for Advanced Medical Technologies

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document addresses a petition for reconsideration (petition) filed by Medtronic, Inc. (Medtronic) regarding rules for the Medical Device Radiocommunication (MedRadio) service. The Commission grants reconsideration to the extent of amending the MedRadio rules to permit the submission of average power transmitter measurements, and making editorial corrections or clarifications to several provisions concerning the frequency monitoring criteria and permissible communications for “listen-before-talk” (LBT) and non-LBT devices. The Commission denies reconsideration in all other respects and otherwise affirms certain provisions of the MedRadio rules questioned by Medtronic.

**DATES:** Effective September 27, 2010.

**FOR FURTHER INFORMATION CONTACT:** Mark Settle, (202) 418-1569 or Gary Thayer, Policy and Rules Division, Office of Engineering and Technology, (202) 418-2290, [Mark.Settle@fcc.gov](mailto:Mark.Settle@fcc.gov) or [Gary.Thayer@fcc.gov](mailto:Gary.Thayer@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s *Memorandum Opinion and Order*, ET Docket No. 06-135, adopted July 15, 2010, and released July 26, 2010. The full text of this document is available on the Commission’s Internet site at <http://www.fcc.gov>. It is also available for inspection and copying during regular business hours in the FCC Reference Center (Room CY-A257), 445 12th Street, SW., Washington, DC 20554. The full text of this document also may be purchased from the Commission’s duplication contractor, Best Copy and Printing Inc., Portals II, 445 12th St., SW., Room CY-B402, Washington, DC 20554; telephone (202) 488-5300; fax (202) 488-5563; e-mail [FCC@BCPIWEB.COM](mailto:FCC@BCPIWEB.COM).

#### Summary of the Memorandum Opinion and Order

1. The Commission addresses a petition for reconsideration (petition) filed by Medtronic, Inc. (Medtronic) regarding rules for the Medical Device Radio-communication (MedRadio) service. The Commission granted reconsideration to the extent of amending the MedRadio rules to permit the submission of average power transmitter measurements, and making editorial corrections or clarifications to several provisions concerning the frequency monitoring criteria and permissible communications for “listen-before-talk” (LBT) and non-LBT devices. The Commission denied reconsideration in all other respects and otherwise affirmed certain provisions of the MedRadio rules questioned by Medtronic.

2. The Commission established the MedRadio service under part 95 of the rules by *Report and Order (MedRadio Order)*, see 74 FR 22696, May 14, 2009. 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. In the *MedRadio Order*, the Commission also adopted service and technical rules governing the operation of medical radiocommunication devices used in the MedRadio service. Building upon the former Medical Implant Communications Service (MICS)—which limited operation to implanted medical devices—the more flexible MedRadio rules accommodate body-worn as well as implanted medical devices, including those using either LBT or non-LBT spectrum access methods. The 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. The MedRadio service continues to incorporate many of the licensing and technical requirements that applied to the legacy MICS.

3. Medtronic requests that the new MedRadio rules be amended to permit transmitter power measurements to be made using average power instrumentation techniques that were formerly allowed under the MICS rules. The former MICS rules stated that compliance with the maximum transmitter power limits shall be based upon measurements using a peak

detector function or, alternatively, the instrumentation techniques set forth in a particular American National Standards Institute (ANSI) standard referenced in the rule. That standard has been modified by ANSI since adoption of the MICS rules in 1999 and no longer includes the specific average power instrumentation techniques cited by Medtronic. As adopted in the *MedRadio Order*, the new rules set forth a compliance requirement in terms of a “Commission-approved peak power technique.” Medtronic argues that the Commission did not propose to delete these provisions of the MICS rules in the *Notice of Proposed Rulemaking (MedRadio NPRM)* that preceded the adoption of the MedRadio rules, see 71 FR 43682, August 2, 2006. Medtronic further asserts that the peak power requirement as set forth in the rule adopted in the *MedRadio Order* would, in effect, prohibit the use of average power instrumentation techniques that were acceptable within the scope of the former MICS rule. It contends that the inability to rely upon these average power techniques for compliance would require MedRadio devices to reduce power, and that this, in turn, would be detrimental to the reliable operation of existing equipment and adversely affect the development of new generation devices. To remedy this concern, Medtronic recommends that the Commission reinstate the former MICS rule provision or, in the alternative, restore the intent of the prior rule by substituting text that would permit the use of average power measurement techniques. St. Jude Medical agrees with Medtronic, stating that the effect of the peak power measurement rule will be to sharply reduce the range available to some systems. Biotronik opposes Medtronic’s request, stating that the peak power approach adopted in the *MedRadio Order* is a more appropriate technique for MedRadio transmitters because average power measurements would allow higher power devices in the band and, thus, increase the potential for interference in the band.

4. As a threshold matter, the Commission addresses Medtronic’s suggestion that it failed to provide sufficient notice for modifying the power measurement provisions. While the Commission acknowledges that the *MedRadio NPRM* did not explicitly request comment on whether the power measurement provisions should be modified, changes to these measurement provisions are a logical outgrowth of issues in the *MedRadio NPRM* that we did present for comment. More specifically, the Commission

specifically invited comment on power and duty cycle thresholds for MedRadio devices and emphasized that its proposed rules were intended to allow flexibility in spectrum usage for MedRadio devices. Thus, it would be reasonable for interested parties to anticipate that the Commission would also adopt rules for determining whether such devices comply with those rules, including power measurement methods. In addition, in the *MedRadio NPRM*, the Commission sought comment on “whether the various current MICS rules would continue to be appropriate for operations under the new allocation.” Parties should have anticipated that the Commission could conclude that a reference to an outdated ANSI standard would not “continue to be appropriate for operations under the new allocation.” Accordingly, the Commission concluded that the power measurement rule revisions adopted in the *MedRadio Order* are logical outgrowths of the *MedRadio NPRM*, and therefore, that the Commission provided sufficient APA notice for these revisions.

5. The Commission notes 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, but recognizes that removing the reference to the obsolete ANSI standard (in combination with the reference to the alternative power measurement technique using a peak detector function) contributed to the uncertainty over whether a previously acceptable average power measurement technique would continue to be allowed. Accordingly, the Commission is amending § 95.628(g)(3) of the *MedRadio* rules to restore the approach in the former MICS rule which specified a peak detector function as one measurement technique for demonstrating compliance with transmitter power limits. In substitution for the obsolete ANSI standard of the former MICS rule, the Commission is also adding a provision that expands the available options for demonstrating compliance by stating that measurement procedures found acceptable to the Commission in accordance with 47 CFR 2.947 may also be used. In addition, the Office of Engineering and Technology (OET) Laboratory Division has published information in its Knowledge Data Base (KDB) concerning acceptable average power measurement procedures under this provision. The Commission believes that this approach satisfies the substance of Medtronic’s request that

the *MedRadio* rules be modified to permit the average power instrumentation techniques formerly acceptable under the MICS rules.

6. This approach also provides greater flexibility than the former MICS rule, which, in part, relied upon the ANSI standards, because it avoids inadvertent rule obsolescence as industry standards are modified or new measurement techniques are developed. Under its Part 2 rules, the Commission can provide specific guidance as to the measurement approaches that are acceptable through the issuance of bulletins or reports—such as recently has been provided in the OET KDB noted in the Memorandum Opinion and Order—and without the need to correct outdated references in the underlying rules through time-consuming, formal proceedings. Moreover, in the event the Commission has not provided guidance on a particular matter through bulletins or reports, the rules also allow parties to provide a detailed description of the measurement procedures actually used for the Commission’s consideration in determining compliance with its technical rules.

7. *Non-LBT devices.* Regarding the frequency monitoring criteria for non-LBT devices, Medtronic correctly points out in its petition that the text of the *MedRadio Order* limits the number of transmissions per hour for non-LBT devices, but that these restrictions were omitted from the appropriate paragraph of § 95.628 (“*MedRadio Transmitters*”) as adopted. Medtronic requests that these limitations be added to paragraphs (b)(2) through (b)(4)—the paragraphs which also specify the duty cycle limits for non-LBT devices. The Commission concurs. The text of the *MedRadio Order* explicitly states that maximum number of communication sessions per hour for non-LBT devices shall be ten (10) per hour for devices operating with 0.01% duty cycle within the 402–405 MHz core band, and one hundred (100) per hour for devices operating with 0.1% duty cycle in the wing bands. The omission of these provisions from the adopted rule was an editorial oversight. Therefore, the Commission amends § 95.628, paragraphs (b)(2) through (b)(4) to add these limits to conform to the literal intent of the *MedRadio Order*.

8. Medtronic also states that § 95.1209(d) (“*Permissible Communications*”) as adopted appears to contain unnecessary language that could be interpreted as allowing non-LBT devices to operate without the communication of data. Medtronic argues that such non-data transmissions are inappropriate for non-LBT devices which do not employ frequency

monitoring pursuant to § 95.628(b). Biotronik also supports this request for the same reasons. In the same subsection, Medtronic points out a clerical error in the text which mismatches the cross-references to limits set forth in § 95.628, subsections (b)(3) through (b)(4), with respect to non-LBT devices operating with 0.1% or 0.01% duty cycles.

9. The Commission agrees that the rules should be changed as Medtronic requests. The reference to non-LBT devices operating “without the communication of data” in § 95.1209(d) as adopted in the *MedRadio Order* was inadvertently carried over from the legacy MICS rule provisions. Historically, MICS devices were limited to LBT operation. Further, as Medtronic correctly points out, some small amount of non-data transmission is necessary to perform the LBT frequency monitoring protocol prescribed in the rules. By comparison, the new *MedRadio* rules encompass the operation of non-LBT as well as LBT devices. Since non-LBT devices, by definition, do not employ frequency monitoring prior to transmitting data, it would be spectrally inefficient and contrary to the intent of the *MedRadio Order* for such devices to operate without the transmission of data.

10. Thus, the Commission amends § 95.1209(d) to remove the reference to non-LBT devices operating without the communication of data. In addition, the Commission rectifies the cross references to the appropriate duty cycle and maximum transmission limits set forth in § 95.628—namely, that non-LBT devices operating pursuant to § 95.628, subsections (b)(2) and (b)(3), with 0.1% duty cycle may transmit for no more than 3.6 seconds per hour; and that non-LBT devices operating pursuant to § 95.628, subsection (b)(4), with 0.01% duty cycle may transmit for no more than 360 milliseconds per hour.

11. *LBT Devices.* The frequency monitoring rules for LBT devices require that the devices monitor channel(s) that they intend to occupy but not initiate a communications session unless certain access criteria are met. These criteria include a threshold power level; the LBT device may use a channel if no signal above the threshold power level is detected on that channel or, if no monitored channel meets this requirement, the channel with the lowest ambient power level (the “least-interfered-channel” or “LIC”). Medtronic urges the Commission to amend the *MedRadio* rules to clarify that single-channel LBT devices operating under the LIC provisions of § 95.628(a)(4) must wait to transmit until the monitoring

threshold power level specified in § 95.628(a)(1) is not exceeded on the device's single channel of operation. Medtronic states its belief that this interpretation was intended by the *MedRadio Order*, but nevertheless seeks clarification to resolve any ambiguity. More specifically, Medtronic observes that the rule's language tacitly envisions MedRadio transmitters capable of operating on multiple channels—such that the availability of an alternate channel is a meaningful option. In this light, Medtronic argues that a strained reading as applied to single channel LBT devices—which, by definition, cannot operate on an alternate channel—could lead to the interpretation that such devices may transmit at will regardless of whether the LBT monitoring threshold had been met. Such an interpretation, Medtronic argues, would essentially write the LBT requirement out of the rule for single channel devices. Biotronik supports this request.

12. The Commission agrees that the rules should be amended to state this clarification. The intended interpretation is that the LBT threshold requirement applies to both multi- and single-channel devices. It also concurs with Medtronic's assertion that a contrary interpretation would obviate the LBT requirement for single channel devices, thereby undermining our goal of fostering equitable band sharing by all LBT devices. Further, while the Commission believes that the contrary characterization that Medtronic cautions against would be a strained reading of the rule, it nevertheless wishes to prevent any misunderstanding. Accordingly, as applied to single channel LBT devices, the Commission clarifies that § 95.628(a)(4) shall be interpreted to require that such devices must wait to transmit until the monitoring threshold on the single channel of operation is not exceeded. The Commission is adding text to § 95.628(a)(4) reflecting this clarification.

13. Medtronic also requested that the Commission clarify that a MedRadio device operating under the LIC provisions of § 95.628(a)(4) must monitor—and be capable of operating on—a specified minimum number of channels (e.g., 9 for the core band, and 18 for the wing bands). With support from Biotronik, Medtronic argues that such a requirement would ensure that devices using the least interfered channel provisions of § 95.628(a)(4) operate on the remaining alternate channels that have the lowest ambient power levels, thereby fostering more

efficient band sharing while minimizing mutual interference.

14. The Commission declines to modify the rule and affirms the rule as adopted. As an initial matter, the Commission notes that no such requirement was contained in the former MICS rules, and that no mention of adopting such a requirement was made in the *MedRadio NPRM*. Furthermore, and on the merits, the Commission also finds that establishing such a requirement on reconsideration would be inconsistent with our general desire, as articulated in the *MedRadio Order*, to adopt rules generally in conformance with the MICS while providing greater flexibility. The Commission believes that it is desirable to give manufacturers and the marketplace ample opportunity to determine the device channeling capabilities that are most useful for a particular application. Thus far, no problems have been reported to us resulting from this flexibility, and Medtronic presents no facts that would cause us to reconsider this decision.

15. Finally, Medtronic asks that the Commission reconsider the decision in the *MedRadio Order* to reject Medtronic's request—which it first raised in a January 10, 2008 *ex parte* submission—to modify the LBT monitoring threshold set forth in § 95.628(a)(3) for devices that transmit with less than the maximum allowed power. The Commission declined to modify the LBT monitoring threshold because the issue was not raised in the *MedRadio NPRM* and thus there was little substantive basis on the record for modifying the rule. At the time of its submission, Medtronic asked that LBT threshold specified in the MICS rules be modified to increase the LBT threshold by 1 db for every 1 dB that the EIRP of the monitoring systems transmitter is below the maximum permitted level of 25 microwatts EIRP for both body-worn and implanted MedRadio devices across the entire 401–406 MHz MedRadio band. Medtronic further stated that this modification would harmonize with recently adopted ETSI standards for low-power medical device data communications in other countries. Medtronic merely reiterates these claims in its petition, and suggests that the requested modification would only affect devices with lower interference potential. More recently, in subsequent *ex parte* submissions, Medtronic characterizes its request as being limited to body-worn devices when acting as programmer/control transmitters, and that it is not seeking a change to the LBT threshold for standalone programmer/control transmitters.

16. Upon reconsideration, the Commission affirms the finding in the *MedRadio Order* that insufficient notice was provided in the *MedRadio NPRM* to support modifying the LBT threshold as requested. The mere fact that Medtronic raised the subject of a modified LBT threshold for the first time in an *ex parte* submission does not cure this basic lack of sufficient notice in the *MedRadio NPRM* itself.

17. The Commission also affirms the finding in the *MedRadio Order* that there was insufficient substantive discussion in the comment record to support such a modification. The Commission believes that modifying the monitoring threshold as suggested by Medtronic raises several issues that require further analysis. For example, Medtronic states that this modification would harmonize with recently adopted ETSI standards for low-power medical device data communications in other countries, but seeks to limit its application to only body-worn devices when acting as programmer/control transmitters across the entire 401–406 MHz MedRadio band. Although the ETSI standard cited by Medtronic does include the substance of the modified LBT threshold, this standard only covers the 401–402 MHz and 405–406 MHz wing bands, and also applies to both implanted and body-worn devices when used to select the frequency of operation. In addition, the Commission has to consider the impact of a higher monitoring threshold on primary METAIDS users in these frequency bands which might increase the likelihood of a medical device seeking to operate on a channel being used by a METAIDS device. Medtronic seeks to minimize these concerns by asserting that LBT medical devices would suffer no more interference from METAIDS devices than non-LBT devices, but it offers no analysis to support this assertion. These concerns lead us to conclude that insufficient substantive record has been developed to act on Medtronic's request at this time. The first step to develop such a record, to the extent it wishes to further proceed on this question, is for Medtronic to file a petition for rulemaking with the Commission.

18. *Human Torso Simulator and Testing Technique*. The transmitters used for medical implant and body-worn devices authorized under the MedRadio rules are required to be tested to determine compliance with radiated emissions and EIRP limits. Medtronic requests that the rules be modified to reinstate a provision requiring use of a particular human torso simulator test technique for implanted medical

devices that was set forth in former § 95.639(f)(2)(i) of the MICS rules. Medtronic states that the corresponding new MedRadio provision, § 95.628(g)(3)(i), which more broadly requires a “Commission-approved human body simulator and test technique,” fails to provide sufficient guidance about what type of measurement data is required. Medtronic also claims that no changes to the test technique were proposed in the *MedRadio NPRM*. Medtronic further argues that the former MICS provision reduces possible confusion by providing, in effect, a safe harbor for compliance purposes. Biotronik supports this request for the same reasons.

19. The Commission denies this request and affirms § 95.628(g)(3)(i) of the new MedRadio rules as adopted. The new rule is more permissive than the former MICS rule and provides greater flexibility in testing devices by expanding, rather than limiting, available measurement compliance options. As the Commission observed regarding procedures for measuring average power, § 2.947 of the rules allows the Commission to provide specific guidance as to the measurement approaches that would be acceptable in a more responsive and timely manner through the issuance of bulletins or reports and without the need to correct outdated references in the underlying rules through time-consuming, formal proceedings. Moreover, in the event the Commission has not provided guidance through bulletins or reports, the rules also allow parties to provide a detailed description of the measurement procedures actually used for the Commission’s consideration in determining compliance with its technical rules. This approach also forestalls inadvertent rule obsolescence as new measurement techniques are developed. More to the point with respect to Medtronic’s concerns herein, the Commission affirms that the new rules do not preclude use of the “human torso” simulator described in the former MICS rules. Finally, as with the transmitter power measurement issue, the Commission notes that the OET Laboratory Division has published information in its KDB concerning acceptable measurement procedures under this provision, including a statement that use of the human torso technique formerly codified in the MICS rules continues to be acceptable.

#### Paperwork Reduction Analysis

20. This document does not contain new or modified information collection requirements subject to the Paperwork

Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

#### Congressional Review Act

21. The Commission will send a copy of this Memorandum Opinion and Order, in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

#### Final Regulatory Flexibility Analysis

22. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),<sup>1</sup> an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rulemaking (MedRadio NPRM)* in this proceeding.<sup>2</sup> The Commission sought written public comment on the proposals in the *MedRadio NPRM*, including comment on the IRFA. In addition, a Final Regulatory Flexibility Analysis (FRFA) was incorporated in the subsequent *Report and Order (MedRadio Order)* in this same proceeding.<sup>3</sup> This Final Regulatory Flexibility Analysis (FRFA) for the subject Memorandum Opinion and Order conforms to the RFA.<sup>4</sup>

#### A. Need for and Objective of Adopted Rules

23. The subject Memorandum Opinion and Order responds to the

<sup>1</sup> *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

<sup>2</sup> *See* Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission’s Rules to Establish the Medical Device Radio Communications Service at 401–402 and 405–406 MHz, Dexcom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 06–135, RM–11271, *Notice of Proposed Rule Making and Notice of Inquiry and Order, (MedRadio NPRM)* 21 FCC Rcd 8164 (2006).

<sup>3</sup> *See* Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission’s Rules to Establish the Medical Device Radio Communications Service at 401–402 and 405–406 MHz, Dexcom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 06–135, RM–11271, *Report and Order, (MedRadio Report and Order)* 24 FCC Rcd 22696 (2009).

<sup>4</sup> *See* 5 U.S.C. 604.

Petition for Reconsideration submitted by Medtronic, Inc. on June 15, 2009.<sup>5</sup> 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.

24. The need for and objectives of the amended rules adopted in this Memorandum Opinion and Order are the same as those discussed in the FRFA for the Report and *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* accommodate 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.<sup>6</sup> 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

<sup>5</sup> *See* *Petition for Reconsideration*, ET Docket No. 06–135, filed by Medtronic on June 15, 2009.

<sup>6</sup> Part 95 governs the Personal Radio Services, including General Mobile Radio Service, Radio Control Service and Citizens Band (CB) Radio Service. The CB Radio Service, in turn, covers a number of specialized services, including the MedRadio Service. As with the legacy MICS, the MedRadio service devices operate on a secondary, non-interference basis with respect to primary authorized services and, as such, they must accept harmful interference from devices operated under such services. Further, MedRadio devices operate on a shared, non-exclusive basis with respect to each other and other secondary devices.

diverse range of diagnostic and therapeutic purposes in humans.

*B. Summary of Significant Issues Raised by Public Comments in Response to the FRFA*

25. No comments were filed in response to the FRFA in this proceeding. In addition, no comments were submitted concerning small business issues.

*C. Description and Estimate of the Number of Small Entities to Which the Adopted Rules Will Apply*

26. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.<sup>7</sup> The RFA generally defines the term “small entity” as having the same meaning as the terms “small business,” “small organization,” and “small governmental jurisdiction.”<sup>8</sup> In addition, the term “small business” has the same meaning as the term “small business concern” under the Small Business Act.<sup>9</sup> A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.<sup>10</sup>

27. In the FRFA the Commission stated that nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.<sup>11</sup> A “small organization” is generally “any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.”<sup>12</sup> Nationwide, as of 2002, there were approximately 1.6 million small organizations.<sup>13</sup> The term “small governmental jurisdiction” is defined generally as “governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.”<sup>14</sup> Census Bureau data for 2002 indicate that there were 87,525

local governmental jurisdictions in the United States.<sup>15</sup> The Commission estimates that, of this total, 84,377 entities were “small governmental jurisdictions.”<sup>16</sup> Thus, we estimate that most governmental jurisdictions are small.

28. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* The Census Bureau defines this category as follows: “This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.”<sup>17</sup> The SBA has developed a small business size standard for firms in this category, which is: all such firms having 750 or fewer employees.<sup>18</sup> According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year.<sup>19</sup> Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999.<sup>20</sup> Thus, under this size standard, the majority of firms can be considered small.

<sup>15</sup> U.S. Census Bureau, Statistical Abstract of the United States: 2006, Section 8, page 272, Table 415.

<sup>16</sup> We assume that the villages, school districts, and special districts are small, and total 48,558. See U.S. Census Bureau, Statistical Abstract of the United States: 2006, section 8, page 273, Table 417. For 2002, Census Bureau data indicate that the total number of county, municipal, and township governments nationwide was 38,967, of which 35,819 were small. *Id.*

<sup>17</sup> U.S. Census Bureau, 2007 NAICS Definitions, “334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing”; <http://www.census.gov/naics/2007/def/ND334220.HTM#N334220>.

<sup>18</sup> 13 CFR 121.201, NAICS code 334220.

<sup>19</sup> U.S. Census Bureau, American FactFinder, 2002 Economic Census, Industry Series, Industry Statistics by Employment Size, NAICS code 334220 (released May 26, 2005); <http://factfinder.census.gov>. The number of “establishments” is a less helpful indicator of small business prevalence in this context than would be the number of “firms” or “companies,” because the latter take into account the concept of common ownership or control. Any single physical location for an entity is an establishment, even though that location may be owned by a different establishment. Thus, the numbers given may reflect inflated numbers of businesses in this category, including the numbers of small businesses. In this category, the Census breaks out data for firms or companies only to give the total number of such entities for 2002, which was 929.

<sup>20</sup> *Id.* An additional 18 establishments had employment of 1,000 or more.

*D. Description of Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities*

29. 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*. As stated above, the only substantive rule change in the Memorandum Opinion and Order merely reinstates a provision from the former MICS rules that permits the submission of average power transmitter measurements.

30. Furthermore, as stated in the FRFA, the rules adopted by the Commission in the *MedRadio Order* use the same licensing approach for the entire 401–406 MHz MedRadio band that was previously used for the legacy MICS band at 402–405 MHz. Rather than require individual transmitter licensing, the Commission authorizes operation by rule within the Citizens Band (CB) Radio Service under Part 95 of our Rules and pursuant to Section 307(e) of the Communications Act.<sup>21</sup> Thus, licensing will be accomplished through adherence to applicable technical standards and other operating rules. The Commission concluded in the *MedRadio Order* that this approach is beneficial because it would minimize the administrative burden on prospective licensees as compared with an individual licensing scheme.

*E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered*

31. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.<sup>22</sup>

<sup>21</sup> We note that 47 U.S.C. 307(e)(3) provides that the term “citizens band radio service” shall have the meaning given it by the Commission by rule. 47 U.S.C. 307(e)(1) provides that upon determination by the Commission that an authorization serves the public interest, convenience, and necessity, the Commission may by rule authorize the operation of radio stations without individual licenses in the citizens band radio service.

<sup>22</sup> See 5 U.S.C. 603(c).

<sup>7</sup> 5 U.S.C. 603(b)(3).

<sup>8</sup> 5 U.S.C. 601(6).

<sup>9</sup> 5 U.S.C. 601(3) (incorporating by reference the definition of “small business concern” in 15 U.S.C. 632). Pursuant to the RFA, the statutory definition of a small business applies “unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.” 5 U.S.C. 601(3).

<sup>10</sup> Small Business Act, 15 U.S.C. 632 (1996).

<sup>11</sup> See SBA, Programs and Services, SBA Pamphlet No. CO-0028, at page 40 (July 2002).

<sup>12</sup> 5 U.S.C. 601(4).

<sup>13</sup> Independent Sector, *The New Nonprofit Almanac & Desk Reference* (2002).

<sup>14</sup> 5 U.S.C. 601(5).

32. In the preceding *MedRadio NPRM*, the Commission sought comment on which regulatory approaches would be appropriate to govern the MedRadio Service. Subsequently, in the *MedRadio Order* the Commission considered the responsive comments filed by interested parties, and determined that record as a whole supported extending the license-by-rule approach under Part 95—used by the former MICS—to the new MedRadio service because of the reduced regulatory impact on all licensees.

#### F. Report to Congress

33. The Commission will send a copy of the Memorandum Opinion and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act.<sup>23</sup> In addition, the Commission's Consumer and Governmental Affairs Bureau will send a copy of the Memorandum Opinion and Order, including the FRFA, to the Chief Counsel for Advocacy of the SBA.

#### Ordering Clauses

34. Pursuant to the authority contained in §§ 4(i), 302, 303(e), 303(f), and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 302, 303(c), 303(f), and 307 this Memorandum Opinion and Order is hereby adopted.

35. Part 95 of the Commission's rules is amended and such rule amendments shall be effective September 27, 2010

36. Pursuant to §§ 4(i), 302, 303(e), 303(f), 303(g), 303(r) and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 302, 303(e), 303(f), 303(g) and 405, that the petition for reconsideration filed by Medtronic, Inc. is granted in part and denied in part as set forth.

37. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this Memorandum Opinion and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

38. It is further ordered that ET Docket No. 06–135 is terminated.

#### List of Subjects in 47 CFR Part 95

Communications equipment, Medical devices.

Federal Communications Commission.

**Marlene H. Dortch**,  
Secretary.

#### Final Rules

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 95 to read as follows:

#### PART 95—PERSONAL RADIO SERVICES

■ 1. The authority citation for part 95 continues to read as follows:

**Authority:** Sections 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303.

■ 2. Section 95.628 is amended by revising paragraphs (a)(4), (b)(2) through (b)(4), and (g)(3) introductory text to read as follows:

#### § 95.628 MedRadio transmitters.

(a) \* \* \*

(4) If no signal in a MedRadio channel above the monitoring threshold power level is detected, the MedRadio programmer/control transmitter may initiate a MedRadio-communications session involving transmissions to and from a medical implant or medical body-worn device on that channel. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, MedRadio transmitters that are capable of operating on multiple channels may transmit on the alternate channel accessible by the device with the lowest monitored ambient power level. Except as provided in paragraph (b) of this section, MedRadio transmitters that operate on a single channel and thus do not have the capability of operating on alternate channels may not transmit unless no signal on the single channel of operation exceeds the monitoring threshold power level.

\* \* \* \* \*

(b) \* \* \*

(2) MedRadio devices operating in either the 401–401.85 MHz or 405–406 MHz bands, provided that the transmit power is not greater than 250 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval, and a maximum of 100 transmissions per hour.

(3) MedRadio devices operating in the 401.85–402 MHz band, provided that the transmit power is not greater than 25 microwatts EIRP and the duty cycle for such transmissions does not exceed

0.1%, based on the total transmission time during a one hour interval, and a maximum of 100 transmissions per hour.

(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.

\* \* \* \* \*

(g) \* \* \*

(3) Radiated emissions and EIRP measurements may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Compliance with the maximum transmitter power requirements set forth in § 95.639(f) shall be based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, measurement procedures that have been found to be acceptable to the Commission in accordance with § 2.947 of this chapter may be used to demonstrate compliance.

\* \* \* \* \*

■ 3. Section 95.1209 is amended by revising paragraph (d) to read as follows:

#### § 95.1209 Permissible communications.

\* \* \* \* \*

(d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.628, MedRadio transmitters may transmit in accordance with the provisions of § 95.628(a) for no more than 5 seconds without the communications of data; MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(2) and (b)(3) for no more than 3.6 seconds in total within a one hour time period; and MedRadio transmitters may transmit in accordance with the provisions of § 95.628(b)(4) for no more than 360

<sup>23</sup> See 5 U.S.C. 801(a)(1)(A).

milliseconds in total within a one hour time period.

\* \* \* \* \*

[FR Doc. 2010-21011 Filed 8-25-10; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 0910131363-0087-02]

RIN 0648-XY45

#### Fisheries of the Economic Exclusive Zone Off Alaska; Pacific Cod in the Bering Sea and Aleutian Islands

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; modification of a closure.

**SUMMARY:** NMFS is opening directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to fully use the 2010 total allowable catch (TAC) of Pacific cod specified for catcher vessels less than 60 feet (18.3 meters) LOA using hook-and-line or pot gear specified for the BSAI.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), August 27, 2010, through 2400 hrs, A.l.t., December 31, 2010. Comments must be received at the following address no later than 4:30 p.m., A.l.t., September 10, 2010.

**ADDRESSES:** Send comments to Sue Salvesson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by RIN 0648-XY45, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal <http://www.regulations.gov>.
- Mail: P.O. Box 21668, Juneau, AK 99802.
- Fax: (907) 586-7557.
- Hand delivery to the Federal Building: 709 West 9th Street, Room 420A, Juneau, AK.

All comments received are a part of the public record. No comments will be posted to <http://www.regulations.gov> for public viewing until after the comment

period has closed. Comment will generally be posted without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Obren Davis, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

NMFS closed directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI under § 679.20(d)(1)(iii) on May 19, 2010 (75 FR 28502, May 21, 2010).

NMFS has determined that as of August 20, 2010, approximately 500 metric tons of Pacific cod remain in the 2010 Pacific cod apportionment for catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI. Therefore, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully use the 2010 TAC of Pacific cod in the BSAI, NMFS is terminating the previous closure and is opening directed fishing for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI.

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public

interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the opening of the Pacific cod fishery by Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet and processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of August 20, 2010.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Without this inseason adjustment, NMFS could not allow the fishery for Pacific cod by catcher vessels less than 60 feet (18.3 meters) length overall using hook-and-line or pot gear in the BSAI to be harvested in an expedient manner and in accordance with the regulatory schedule. Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until September 10, 2010.

This action is required by § 679.25 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: August 23, 2010.

**Carrie Selberg,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2010-21260 Filed 8-23-10; 4:15 pm]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 0910131363-0087-02]

RIN 0648-XY44

#### Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; reallocation.