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DISPATCHED BY  
 Before the  
 Federal Communications Commission  
 Washington, D.C. 20554

In the Matter of )  
 )  
 Amendment of Parts 2 and 95 ) WT Docket No. 99-66  
 of the Commission's Rules ) RM-9157  
 to Establish a Medical Implant )  
 Communications Service in the )  
 402-405 MHz Band )

**REPORT AND ORDER**

**Adopted:** November 19, 1999

**Released:** November 29, 1999

By the Commission:

**I. INTRODUCTION AND EXECUTIVE SUMMARY**

1. On February 12, 1999, we proposed to establish a Medical Implant Communications Service ("MICS"), operating in the 402-405 MHz frequency band, to permit the utilization of newly-developed, ultra-low power medical implant devices, such as cardiac pacemakers and defibrillators.<sup>1</sup> MICS was proposed as an ultra-low power, unlicensed, mobile radio service for transmitting data in support of the diagnostic and/or therapeutic functions associated with implanted medical devices. The establishment of the MICS would enable individuals and medical practitioners to utilize potential life-saving medical technology without causing interference to other users of the spectrum. Because of the unanimous support given our proposals, this *Report and Order* ("*Report and Order*") adopts the proposed rules with certain minor modifications as suggested by the comments in this proceeding.

**II. BACKGROUND**

2. On July 28, 1997, Medtronic, Inc. ("Medtronic") filed a Petition for Rule Making ("*Petition*"), requesting amendment of our Rules to establish a MICS for operation in the 402-405 MHz band.<sup>2</sup> The Petition requested that we issue a notice of proposed rulemaking to: (a) amend the Table of Allocations at Section 2.106 of our Rules to accord MICS a secondary allocation in the 402-403 and 403-405 MHz bands, and (b) revise Part 95 of our Rules to permit the operation of ultra-low

<sup>1</sup>Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Notice of Proposed Rule Making*, WT Docket No. 99-66, RM-9157, FCC 99-23, 64 Fed. Reg. 10266 (1999) ("*Notice*").

<sup>2</sup>The 402-405 MHz band is part of the spectrum allocated to the Meteorological Aids ("*Met aids*") service. See 47 C.F.R. § 2.106, Table of Frequency Allocations.

power MICS transmitters in those bands without an individual license issued by the FCC.<sup>3</sup> In response to the Petition, we proposed to: (a) allocate the 402-405 MHz band to the mobile service; (b) designate this allocation for MICS operations on a shared, non-interference basis; (c) establish the MICS within the Citizens Band ("CB") Radio Service under Part 95 of our Rules<sup>4</sup> and; (d) authorize operation in the MICS by rule pursuant to Section 307(e) of the Communications Act.<sup>5</sup> Eight parties filed comments in response to the *Notice*.<sup>6</sup>

### III. DISCUSSION

#### A. *Establishment of the MICS*

3. Operation of current medical implant devices require that they be magnetically coupled to external programmers or readers. Magnetic coupling requires very close spacings between the implanted device in the patient and external monitoring/control equipment, often requiring body contact for proper operation. Current devices also operate with very slow data rates, sometimes requiring up to fifteen minutes for the required data transfer. We tentatively concluded in the *Notice* that establishing a MICS and specifying the technical parameters for newly-developed medical implant devices would overcome the limitations of current medical implant devices.<sup>7</sup> We also concluded that establishing a MICS would greatly improve the utility of medical implant devices by allowing physicians to establish high-speed, easy-to-use, reliable, short-range (six feet) wireless links to connect such devices with monitoring and control equipment.<sup>8</sup>

4. All commenters unanimously supported our proposals regarding the establishment of the MICS. For example, Cardiovascular Consultants, P.C. states that the MICS would provide a breakthrough in the medical implant technology field, and would lead to marked improvement in the ability to interact with these devices, particularly as they become more complex.<sup>9</sup> Similarly,

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<sup>3</sup>Petition for Rulemaking, RM-9157, at 18.

<sup>4</sup>We have previously taken similar action when we included the Family Radio Service and the Low Power Radio Service in the CB Radio Services. See 47 C.F.R. §§ 95.401(b), 95.401(c); see also, Amendment of Part 95 of the Commission's Rules to Establish a Very Short Distance Two-way Voice Radio Service, *Report and Order*, WT Docket No. 95-102, 11 FCC Rcd 12,977 (1996); Amendment of the Commission's Rules Concerning Low Power Radio and Automated Maritime Telecommunications System Operation in the 216-217 MHz Band, *Report and Order*, WT Docket No. 95-56, 11 FCC Rcd 18,517 (1996).

<sup>5</sup>*Notice*, ¶ 14.

<sup>6</sup>Comments were filed by University of Western Ontario, Washington Hospital Center, Douglas P. Zipes, M.D., Medtronic, Cardiovascular Consultants, P.C., American Hospital Association, Iowa Heart Center, P.C., Dr. William Scanlon (late-filed but accepted). Reply comments and ex-parte submissions were filed by Medtronic.

<sup>7</sup>*Notice*, ¶ 7.

<sup>8</sup>*Id.*

<sup>9</sup>Cardiovascular Consultants, P.C. Comments at 1.

Medtronic states that the MICS would permit physicians and their patients to take advantage of the benefits of wireless technology to improve the medical care and capabilities of implanted medical devices, thereby improving these patients' quality of life.<sup>10</sup> Medtronic further argues that the current technology used for communications between medical implant devices and the equipment used to program, monitor and control them is dated and severely restricts the capabilities of existing implant technologies.<sup>11</sup> For example, Medtronic indicates that the slow data exchange rate of current equipment prohibits the use of new developments in implant technology.<sup>12</sup> Medtronic also indicates that the current implant monitoring system increases the risk of infection to patients, requires patients to endure uncomfortable positions, and limits the actions of medical personnel working with the equipment.<sup>13</sup>

5. Other commenters expressed similar views. Dr. Douglas P. Zipes, Krannert Institute of Cardiology, comments that the MICS "is in the public interest because it would enhance patient care and improve treatment options by affording communication with implantable medical services in a manner that is significantly more efficient than current systems."<sup>14</sup> Similarly, the American Hospital Association states that "[T]he establishment of a MICS will enhance patient health and safety by promoting the development of a new generation of implant devices that will provide a safer, less costly, and less invasive method to diagnose and manage patient conditions than the systems currently utilized."<sup>15</sup> We conclude, therefore, that the establishment of a MICS is in the public interest.

#### B. Suitability of the 402-405 MHz Band for the MICS

6. Medtronic, in its Petition, presented a comprehensive analysis of the availability and suitability of spectrum for the MICS.<sup>16</sup> Medtronic concluded that the 402-405 MHz band best satisfies the technical requirements of the MICS. In the *Notice*, we stated that although other spectrum is available for use by physicians and health care providers under Part 15 of our Rules,<sup>17</sup> technical considerations make that spectrum ill-suited for proposed MICS operations because both the 174-216 MHz and the 470-668 MHz bands are outside the range of spectrum generally considered to be the

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<sup>10</sup>Medtronic Comments at 2; *see also* AHA Comments at 1, Iowa Heart Center, P.C. Comments at 1-2 and Washington Hospital Center Comments at 1.

<sup>11</sup>Medtronic Comments at 2-3.

<sup>12</sup>*Id.* at 3-5.

<sup>13</sup>*Id.* at 3.

<sup>14</sup>Dr. Douglas P. Zipes Comments at 2.

<sup>15</sup>American Hospital Association Comments at 1.

<sup>16</sup>Petition at 10-12.

<sup>17</sup>47 C.F.R. Part 15 permits unlicensed operation of biomedical telemetry devices in the 174-216 MHz band (VHF TV channels 7-13) and in the 470-668 MHz band (UHF TV channels 14-46). *See* 47 C.F.R. §§ 15.241 and 15.242.

most suitable for propagation of radio signals within the human body.<sup>18</sup> Further, we stated that medical devices operating in either of those bands must share that spectrum with high power adjacent broadcasting stations which might cause interference.<sup>19</sup> Moreover, we noted that the 174-216 MHz and 470-668 MHz bands do not lend themselves to international compatibility, as does the 402-405 MHz band.<sup>20</sup> Finally, we indicated that MICS operations on available licensed spectrum under Part 90 of our Rules would also be impractical because of similar technical considerations.<sup>21</sup> Therefore, we proposed MICS operation in the 402-405 MHz band.

7. In its comments, Medtronic reiterates that the 402-405 MHz band would be the most appropriate spectrum to facilitate the medical success of the MICS.<sup>22</sup> Medtronic states that in addition to the worldwide availability of the 402-405 MHz band, equipment designed to operate in the band would fully satisfy the technical requirements of the MICS with respect to size, power, antenna performance, and receiver design.<sup>23</sup> Medtronic, therefore, fully supports our proposal to accommodate MICS operation in the 402-405 MHz band. Additionally, in its comments, Medtronic also suggests minor changes to the technical rules proposed in the *Notice* that will reflect the most recent developments in medical implant device technology.<sup>24</sup>

8. Further, Medtronic indicates that the MICS can be implemented in the 402-405 MHz band without interference to shared Metacids operations.<sup>25</sup> Medtronic cites an International Telecommunication Union ("ITU") recommendation which states that sharing is feasible between the MICS and Metacids systems operating in the 401-406 MHz band if the effective isotropic radiated power ("EIRP") of MICS transmitters is limited to 25 microwatts.<sup>26</sup> Medtronic, therefore, asserts that because of the very low power and duty cycle of MICS transmitters, there is virtually no threat of

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<sup>18</sup>*Notice*, ¶ 8.

<sup>19</sup>*Id.*

<sup>20</sup>*Id.*

<sup>21</sup>*Id.*

<sup>22</sup>Medtronic Comments at 5-10.

<sup>23</sup>*Id.* at 6-8.

<sup>24</sup>*Id.* at 10-11.

<sup>25</sup>*See* note 2, *supra*.

<sup>26</sup>In its Petition at 14, Medtronic references the report prepared by the ITU Radiocommunication Study Group, Working Party 7C, Document 7C/TEMP/138-E (5 June 1997). Subsequently, this document was incorporated into ITU-R Recommendation SA1346, "Sharing Between the Meteorological Aids Service and Medical Implant Communications Systems Operating in the Mobile Service in the Frequency Band 401-406 MHz." (February 1998). The rules limit MICS transmitters to a maximum EIRP of 25 microwatts.

interference to any part of the extensive Metatids infrastructure.<sup>27</sup> After consideration of the rationale presented for use of the 402-405 MHz band, we conclude that the 402-405 MHz band is the most suitable for the MICS. We, therefore, amend our Rules to designate the MICS as a shared, secondary operation in the 402-405 MHz band.

### C. Licensing of MICS Operations

9. In the *Notice*, we proposed an administrative approach for the MICS that would minimize regulation.<sup>28</sup> Rather than issue individual station licenses, we proposed to administer the MICS within the CB Radio Service under Part 95 of our Rules,<sup>29</sup> where operation may be authorized by rule pursuant to Section 307(e) of the Communications Act.<sup>30</sup> Administration would be through adherence to transmitter technical standards and operating rules.<sup>31</sup> In the *Notice*, we tentatively concluded that the administrative burdens associated with the individual licensing of MICS operations would outweigh any potential benefits from such licensing, and that no regulatory purpose would be served by requiring station licenses in such a radio service.<sup>32</sup>

10. All comments received on this issue supported our proposal to permit operations in the MICS without a station license.<sup>33</sup> We agree with the commenters. The MICS is a very low power, short-range radio service operating within a closed environment. We do not believe that a data base of licensees in this service will assist us in enforcement efforts or would be useful for spectrum management purposes.<sup>34</sup> Further, we believe that individual licensing in this context would be costly to the public and administratively burdensome to the Commission. Therefore, we are adopting the regulatory approach for the MICS that we proposed. MICS will be administered within the CB Radio Service, operation will be authorized by rule, and administration will be by adherence to technical

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<sup>27</sup>The *Notice* proposed that the MICS be designated as a secondary use of the 402-405 MHz part of the Metatids band to require that remedial action be taken should a MICS operation cause interference to a Metatids system. See *Notice* at Appendix A, § 95.1111.

<sup>28</sup>*Notice*, ¶ 14.

<sup>29</sup>See note 3, *supra*.

<sup>30</sup>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>31</sup>The proposed operating rules cover eligibility, authorized locations, permissible communications, channel use policy and labeling requirements. See *Notice* at Appendix B.

<sup>32</sup>*Notice*, ¶ 14.

<sup>33</sup>Comments of Douglas P. Zipes, M.D. at 1; Comments of the Washington Hospital Center at 1.

<sup>34</sup>See Amendment of Parts 1 and 95 of the Commission's Rules to Eliminate Individual Station Licenses in the Radio Control (RC) Radio Service and the Citizens Band (CB) Radio Service, *Report and Order*, PR Docket No. 82-799, 48 FR 24884, June 3, 1983.

standards, equipment certification requirements and operating rules. In order to assure compliance with the technical standards, we are requiring certification of MICS transmitters.

D. *RF Emission exposure*

11. In the *Notice*,<sup>35</sup> we proposed to exempt MICS transmitters from the requirement for routine evaluation of human exposure to RF emissions pursuant to Section 1.1307(b) of our Rules.<sup>36</sup> We stated that because of the very low proposed EIRP of an implanted MICS transmitter (*i.e.*, 25 microwatts), it appeared unlikely that either patients or medical professionals would be exposed in excess of our radiation exposure limits.<sup>37</sup>

12. In a joint *ex parte* filing, Medtronic and Dr. Wm. Scanlon recommend that we require routine filing by manufacturers of an EA prior to equipment authorization.<sup>38</sup> Medtronic and Dr. Scanlon state that the Medtronic approach may not be the only one employed for medical implant transmitters and that other manufacturers could employ designs and technologies that could potentially cause radiation levels to be at or near current limits.<sup>39</sup> Therefore, Medtronic and Dr. Scanlon recommend that a filing of a certification of compliance with with our RF exposure rules, as required by Section 1.1307, is needed, as it will provide additional assurance that a patient's health and safety are protected.<sup>40</sup> After considering this issue, we agree with the rationale presented by Medtronic and Dr. Scanlon. We conclude that evaluation for RF exposure prior to equipment authorization is appropriate and accordingly will amend Section 1.1307 (b)(2) of our Rules as required.

E. *Equipment Registration*

13. In the *Notice*, we proposed that the holder of the grant of equipment authorization shall include with each medical implant programmer/control transmitter a notice that the entity responsible for the operation of the medical implant programmer/control transmitter shall, before using the device, register with the holder of the grant of equipment authorization.<sup>41</sup> The proposed § 95.1115(b) described the contents to be included in the registration document and procedures for reregistration if control of the device is transferred.

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<sup>35</sup>*Notice*, ¶ 13.

<sup>36</sup>47 C.F.R. § 1.1307(b) requires, when applying for equipment authorization, the preparation of an Environmental Assessment ("EA") if a transmitter would cause human exposure to levels of radio frequency radiation in excess of the limits specified in 47 C.F.R. § 1.1310.

<sup>37</sup>*Notice*, ¶ 13.

<sup>38</sup>Letter Ex Parte Presentation, WT Docket No. 99-66, from Dr. William Scanlon, University of Ulster and Eduardo Villaseca, Medtronic, Inc. to Ms. Magalie Roman Salas, Secretary, Federal Communications Commission (June 18, 1999).

<sup>39</sup>*Id.* at 1.

<sup>40</sup>*Id.*

<sup>41</sup>*Notice*, Appendix B, § 95.1115(b) Disclosure policies and registration..

14. The intent of the proposed rule was to enable the manufacturer or the holder of the grant of equipment authorization of the programmer/control transmitter to establish a data base of the locations of the devices. This data base would be made available to us should interference from a programmer/control transmitter be suspected. Upon further consideration of this proposed rule, we believe that it is not appropriate for us to mandate the registration of transmitting equipment with the manufacturer, nor to specify the details of registration documents. We conclude that mandatory registration is unnecessary and that registration requirements and details should be left to the discretion of the manufacturer or the holder of equipment certification of the device.<sup>42</sup> We, therefore, are not adopting the registration requirement as proposed in §§ 95.1115(b) and 95.1117(a) of Appendix B as contained in the *Notice*.

#### IV. CONCLUSION

15. Considering the support received for our proposals in the *Notice*, for the foregoing reasons, we adopt rules to: (a) amend the Table of Allocations in Section 2.106 of our Rules<sup>43</sup> to allocate the 402-405 MHz band to the mobile service and designate the MICS as a shared operation in the band and; (b) add Subpart I to Part 95 of the Rules,<sup>44</sup> with codified rules to permit the operation of MICS transmitters in the 402-405 MHz band without an individual license issued by the Commission and; (c) amend Section 1.1307(b)(2) of our Rules<sup>45</sup> to require the preparation of environmental evaluation for RF exposure reports prior to obtaining equipment authorization. We believe that the adopted rules will allow use of newly-developed, life-saving medical technology without harming other users of the frequency band.

16. Accordingly, in this *Report and Order*, we adopt rule changes that implement a regulatory framework for the MICS consisting of authorization by rule on the condition that harmful interference is not caused to stations in the Metacids Service and provide for approval of MICS transmitters under our equipment authorization program. We also adopt, with minor revisions, the operational rules and technical standards for the MICS as proposed in the *Notice*. We believe that these rules will ensure that neither Metacids nor MICS operations will experience any interference from sharing the 402-405 MHz band.

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<sup>42</sup>For example, Medtronic states that they will maintain records of the locations of all programmer/controller transmitters to be used with medical implant transmitters made by Medtronic to be operated in the MICS. *See Ex Parte Presentation* Letter from David E. Hilliard, Counsel for Medtronic, to Ms. Magalie Roman Salas, Secretary, Federal Communications Commission (October 27, 1999).

<sup>43</sup>47 C.F.R. § 2.106.

<sup>44</sup>47 C.F.R. Part 95.

<sup>45</sup>47 C.F.R. § 1.1307(b)(2).

## V. PROCEDURAL MATTERS

### Final Regulatory Flexibility Analysis

17. A Final Regulatory Flexibility Analysis has been prepared and is included in Appendix A.

### Alternative Formats

18. Alternative formats (computer diskette, large print, audio cassette and Braille) of this *Report and Order* are available to persons with disabilities by contacting Martha Contee at (202) 418-0260, TTY (202) 418-2555, or at [mcontee@fcc.gov](mailto:mcontee@fcc.gov). This *Report and Order* can also be downloaded at <http://www.fcc.gov/dtf/>.

### Ordering Clauses

19. Accordingly, IT IS ORDERED, pursuant to the authority of Sections 4(i), 303(r), and 332(a)(2) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 303(r), 332(a)(2), Parts 1, 2, and 95 of the Commission's Rules, that 47 C.F.R. Parts 1, 2 and 95 ARE AMENDED as set forth in the attached Appendix B.

20. IT IS FURTHER ORDERED that the rule changes adopted herein will become effective [thirty days after publication in the Federal Register].

21. IT IS FURTHER ORDERED that the Commission's Reference Information Center, Consumer Information Bureau, SHALL SEND a copy of this *Report and Order*, WT Docket No. 99-66, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

22. IT IS FURTHER ORDERED, pursuant to Section 4(i) of the Communications Act of 1934, as amended, 47 U.S.C. § 154(i), that the late-filed comments (e-mail filed on April 9, 1999) by Dr. William Scanlon, ARE ACCEPTED for consideration in this proceeding.

23. IT IS FURTHER ORDERED, pursuant to Section 4(i) of the Communications Act of 1934, as amended, 47 U.S.C. § 154(i), that this proceeding IS TERMINATED.

FEDERAL COMMUNICATIONS COMMISSION



Magalie Roman Salas  
Secretary

## APPENDIX A

## FINAL REGULATORY FLEXIBILITY ANALYSIS (FRFA)

As required by the Regulatory Flexibility Act (RFA),<sup>46</sup> an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice* prepared in this proceeding.<sup>47</sup> The Commission sought written public comment on the proposals in the *Notice*, including comments on the IRFA. This present FRFA conforms to the RFA.<sup>48</sup>

**A. Need for, and Objectives of, the Report and Order:**

1. In this proceeding, we amend Parts 1, 2 and 95 of the Commission's Rules to establish the Medical Implant Communications Service (MICS) as a shared allocation in the Non-Government 402-405 MHz band, and to codify the service rules for the MICS. The adopted rules will permit the use of newly-developed, life-saving medical technology without causing interference to other users of the frequency band.

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

2. No comments were submitted specifically in response to the IRFA.

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

3. 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>49</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>50</sup> In addition, the term "small business"

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<sup>46</sup>See 5 U.S.C. § 603. The RFA, *see* 5 U.S.C. § 601 *et seq.*, has been amended by the Contract with America Advancement Act of 1996, Pub. L. No. 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

<sup>47</sup>See Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Notice of Proposed Rule Making*, WT Docket No. 99-66, RM-9157, FCC 99-23, 64 FR 10266, 10267 (March 3, 1999) (*Notice*).

<sup>48</sup>See 5 U.S.C. § 604.

<sup>49</sup>5 U.S.C. 603(b)(3).

<sup>50</sup>*Id.* 601(6).

has the same meaning as the term "small business concern" under the Small Business Act.<sup>51</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 Small Business Administration (SBA).<sup>52</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>53</sup> Nationwide, as of 1992, there were approximately 275,801 small organizations.<sup>54</sup> "Small governmental jurisdiction" generally means "governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000."<sup>55</sup> As of 1992, there were approximately 85,006 such jurisdictions in the United States.<sup>56</sup> This number includes 38,978 counties, cities, and towns; of these, 37,566, or 96 percent, have populations of fewer than 50,000.<sup>57</sup> The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, we estimate that 81,600 (91 percent) are small entities. Of the estimated 81,600 small governmental entities, many are hospital and health care facilities.

4. In addition, the adopted rules would apply to manufacturers of medical implant devices and users of the proposed MICS equipment, such as hospitals and clinics that are not government health care facilities. According to the SBA's regulations, nursing homes and hospitals must have annual gross receipts of \$5 million or less in order to qualify as a small business concern.<sup>58</sup> There are approximately 11,471 nursing care firms in the nation, of which 7,953 have annual gross receipts of \$5 million or less.<sup>59</sup> There are approximately 3,856 hospital firms in the nation, of which 294 have gross receipts of \$5 million or less. We do not know how many hospitals would actually implement MICS equipment; however, the maximum number of facilities to which the adopted rules would apply is 8,247.

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<sup>51</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>52</sup>Small Business Act, 15 U.S.C. 632 (1996).

<sup>53</sup>5 U.S.C. 601(4).

<sup>54</sup>1992 Economic Census, U.S. Bureau of the Census, Table 6 (special tabulation of data under contract to Office of Advocacy of the U.S. Small Business Administration).

<sup>55</sup>5 U.S.C. 601(5).

<sup>56</sup>U.S. Department of Commerce, Bureau of the Census, "1992 Census of Governments."

<sup>57</sup>*Id.*

<sup>58</sup>13 C.F.R. § 121.201.

<sup>59</sup>See Small Business Administration Tabulation File, SBA Size Standards Table C January 23, 1996, SBA, Standard Industrial Code categories 8050 (Nursing and Personal Care Facilities) and 8060 (Hospitals).

**D. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements:**

5. There is a reporting or recordkeeping requirement that will be imposed as a result of the actions adopted in this rule making proceeding. Manufacturers of medical implant programmer/control transmitters will continue to be required to follow our normal equipment authorization procedures, and include with each transmitting device a statement regarding harmful interference pursuant to §§ 95.1215(a) and 95.1217 of the Rules.

**E. Steps Taken to Minimize Significant Economic Impact on Small Entities and Significant Alternatives Considered:**

6. By making frequency spectrum available, the adopted rules will have a beneficial economic impact on small business entities that would either manufacture, or contribute to the manufacturing of, equipment used in the MICS by enabling these businesses to increase their product lines. In addition, a beneficial, indirect, economic impact affects individuals who are the recipients of implanted MICS devices. While a precise determination of the cost savings is difficult to calculate, two examples are useful. First, over \$15M dollars per year would be saved by eliminating the need to conduct quarterly interrogation of implanted cardiac defibrillators in the clinical setting. This estimate does not include the interrogation of pacemakers, which are implanted at a much higher rate than defibrillators. Second, over \$37B is currently spent annually on hospitalization due to heart failure. When devices currently under development for the management of heart failure incorporate the MICS technology, it is expected that there will be a meaningful reduction in hospitalization costs. Assuming this impact is as small as five percent, the estimated savings would be nearly \$2B per year.<sup>60</sup>

**Report to Congress:** The Commission will send a copy of the *Report and Order*, including this FRFA, in a report to be sent to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, *see* 5 U.S.C. § 801(a)(1)(A). In addition, the Commission will send a copy of the *Report and Order*, including FRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the *Report and Order* and FRFA (or summaries thereof) will also be published in the Federal Register. *See* 5 U.S.C. § 604(b).

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<sup>60</sup>See Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Radio Service in the 402-405 MHz Band, RM-9157, Petition for Rule Making at 6, note 3.

## APPENDIX B - FINAL RULES

Parts 1, 2 and 95 of Title 47 of the Code of Federal Regulations are amended as follows:

**PART 1 PRACTICE AND PROCEDURE**

1. The authority citation for Part 1 continues to read as follows:

**Authority:** 15 U.S.C. 79 *et seq.*; 47 U.S.C. 151, 154(i), 154(j), 155, 225, and 303(r).

2. Section 1.1307 is amended by revising paragraph (b)(2) to read as follows:

**§ 1.1307 Actions which may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.**

\* \* \* \* \*

(b) \* \* \*

(2) Mobile and portable transmitting devices that operate in the Cellular Radiotelephone Service, the Personal Communications Services (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services (ship earth stations only) and the Specialized Mobile Radio Service authorized under Subpart H of Parts 22, 24, 25, 26, 27, 80, and 90 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§ 2.1091 and 2.1093 of this chapter. Unlicensed PCS, unlicensed NII and millimeter wave devices are also subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§ 15.253(f), 15.255(g), 15.319(i), and 15.407(f) of this chapter. Equipment authorized for use in the Medical Implant Communications Service (MICS) as a medical implant transmitter (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in § 2.1093 of this chapter by finite difference time domain computational modeling or laboratory measurement techniques. Where a showing is based on computational modeling, the Commission retains the discretion to request that specific absorption rate measurement data be submitted. All other mobile, portable, and unlicensed transmitting devices are categorically excluded from routine environmental evaluation for RF exposure under §§ 2.1091, 2.1093 of this chapter except as specified in paragraphs (c) and (d) of this section.

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**PART 2 – FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS;  
GENERAL RULES AND REGULATIONS**

3. The authority citation for part 2 continues to read as follows:

**Authority:** 47 U.S.C. sections 154, 302, 303 and 307, unless otherwise noted.

4. In Section 2.106, the Table of Frequency Allocations, is amended by removing the existing entries

for 402-403 MHz and 403-406 MHz, adding new entries in numerical order for 402-403 MHz and 403-406 MHz, and adding footnote US345 in numerical order to read as follows:

§ 2.106 Table of Frequency Allocations.

International table			United States table		FCC use designators	
Region 1 -- allocation MHz	Region 2 -- allocation MHz	Region 3 -- allocation MHz	Government	Non-Government	Rule part(s)	Special-use frequencies
(1)	(2)	(3)	Allocation MHz (4)	Allocation MHz (5)	(6)	(7)
*	*	*	*	*	*	*
402-403 METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	402-403 METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	402-403 METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	402-403 METEOROLOGICAL AIDS (radiosonde) US70 Earth Exploration-Satellite (Earth-to-space) Meteorological Satellite (Earth-to-space)  US345	402-403 METEOROLOGICAL AIDS (radiosonde) US70 Earth Exploration-Satellite (Earth-to-space) Meteorological Satellite (Earth-to-space)  US345	Personal (95)	Medical Implant Communications (MICS)
403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile	403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile	403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile	403-406 METEOROLOGICAL AIDS (radiosonde) US70  US345 G6	403-406 METEOROLOGICAL AIDS (radiosonde) US70  US345	Personal (95)	Medical Implant Communications (MICS)
*	*	*	*	*	*	*

## UNITED STATES (US) FOOTNOTES

\* \* \* \* \*

US345 In the 402-405 MHz band the mobile, except mobile aeronautical, service is allocated on a secondary basis and is limited to, with the exception of military tactical mobile stations, Medical Implant Communications Service (MICS) operations. MICS stations are authorized by rule on the condition that harmful interference is not caused to stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services, and that MICS stations accept interference from stations in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services. Certain MICS stations are subject to the registration requirements set forth in Section 95.1215 of this chapter.

\* \* \* \* \*

5. Section 2.1204 is amended by adding paragraph (a)(9) to read as follows:

**§ 2.1204 Import conditions.**

\* \* \* \* \*

(a) \* \* \*

(9) The radio frequency device is a medical implant transmitter inserted in a person granted entry into the United States or is a medical implant programmer/controller transmitter associated with such an implanted transmitter, provided, however that the transmitters covered by this provision otherwise comply with the technical requirements applicable to transmitters authorized to operate in the Medical Implant Communications Service under Part 95 of this chapter. Such transmitters are permitted to be imported without the issuance of a grant of equipment authorization only for the personal use of the person in whom the medical implant transmitter has been inserted.

**PART 95 - PERSONAL RADIO SERVICES**

6. The authority for Part 95 continues to read as follows: /

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

7. Section 95.401 is amended by adding paragraph (e) to read as follows:

**§ 95.401 (CB Rule 1) What are the Citizens Band Radio Services?**

\* \* \* \* \*

(d) The Medical Implant Communications Service (MICS) - 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 medical devices. The rules for this service are contained in subpart I of this part.

8. Section 95.601 is amended by revising the last sentence in the text to read as follows:

**§ 95.601 Basis and purpose.**

\* \* \* The Personal Radio Services are the GMRS (General Mobile Radio Service)--subpart A, the Family Radio Service (FRS)--subpart B, the R/C (Radio Control Radio Service)--subpart C, the CB (Citizens Band Radio Service)--subpart D, the Low Power Radio Service (LPRS)--subpart G, the Multi-Use Radio Service (MURS)--subpart H, and the Medical Implant Communications Service (MICS)--subpart I.

9. Section 95.603 is amended by adding paragraph (g) to read as follows:

**§ 95.603 Certification required.**

\* \* \* \* \*

(g) Each Medical Implant Communications Service transmitter (a transmitter that operates or is intended to operate in the MICS) must be certificated except for medical implant transmitters that are not marketed for use in the United States, but which otherwise comply with the MICS technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad. Medical implant transmitters (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request the submission of specific absorption rate measurement data.

10. Section 95.605 is amended by revising the first paragraph of the text to read as follows:

**§ 95.605 Certification procedures.**

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, R/C, CB, IVDS, LPRS, MURS or MICS following the procedures in Part 2 of this chapter. Medical implant transmitters shall be tested for emissions and EIRP limit compliance while enclosed in a medium that simulates human body tissue in accordance with the procedures in Section 95.639(g). Frequency stability testing for MICS transmitters shall be performed over the temperature range set forth in § 95.628.

\* \* \* \* \*

11. Section 95.628 is added to read as follows:

**§ 95.628 MICS Transmitter**

(a) Frequency monitoring. Medical implant programmer/control transmitters must incorporate a mechanism for monitoring the channel or channels that the MICS system devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before a medical implant programmer/control transmitter

initiates a MICS communications session, the following access criteria must be met:

(1) The monitoring system bandwidth measured at its 20 dB down points must be equal to or greater than the emission bandwidth of the intended transmission.

(2) Within 5 seconds prior to initiating a communications session, circuitry associated with a medical implant programmer/control transmitter must monitor the channel or channels the MICS system devices intend to occupy for a minimum of 10 milliseconds per channel.

(3) Based on use of an isotropic monitoring system antenna, the monitoring threshold power level must not be more than  $10\log B(\text{Hz}) - 150 (\text{dBm/Hz}) + G(\text{dBi})$  where B is the emission bandwidth of the MICS communication session transmitter having the widest emission and G is the medical implant programmer/control transmitter monitoring system antenna gain relative to an isotropic antenna. For purposes of showing compliance with the above provision, the above calculated threshold power level must be increased or decreased by an amount equal to the monitoring system antenna gain above or below the gain of an isotropic antenna, respectively.

(4) If no signal in a MICS channel above the monitoring threshold power level is detected, the medical implant programmer/control transmitter may initiate a MICS communications session involving transmissions to and from a medical implant device on that channel. The MICS 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, the channel with the lowest ambient power level may be accessed.

(5) When a channel is selected prior to a MICS communications session, it is permissible to select an alternate channel for use if communications is interrupted, provided that the alternate channel selected is the next best choice using the above criteria. The alternate channel may be accessed in the event a communications session is interrupted by interference. The following criteria must be met:

(i) Before transmitting on the alternate channel, the channel must be monitored for a period of at least 10 milliseconds.

(ii) The detected power level during this 10 millisecond or greater monitoring period must be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.

(iii) In the event that this alternate channel provision is not used by the MICS system or if the criteria in (i) and (ii) above are not met, a channel must be selected using the access criteria specified in paragraphs (a)(1)-(a)(4) of this section.

(6) As used in this section, the following definitions apply:

(i) Emission bandwidth - Measured as the width of the signal between the points on either side of carrier center frequency that are 20 dB down relative to the maximum level of the modulated carrier. Compliance will be determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1% of the emission bandwidth of the device under test.

(ii) MICS channel - Any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MICS communications session. (Note: The rules do not specify a channeling scheme for use by MICS systems.)

(iii) MICS communications session - A collection of transmissions, that may or may not be continuous between MICS system devices.

(b) MICS communications sessions initiated by a medical implant event are not required to use the access criteria set forth in paragraph (a) of this section.

(c) Stations may operate on any of the frequencies in the band 402.000 - 405.000 MHz, provided that the out-of-band emissions are attenuated in accordance with § 95.635.

(d) The authorized bandwidth of the emission from a MICS station shall not exceed 300 kHz, and no communications session involving MICS stations shall use more than a total of 300 kHz of bandwidth during such a session. Note: This provision does not preclude full duplex or half duplex communications provided that the total amount of bandwidth utilized by all of the MICS channels employed in such a MICS communications session does not exceed 300 kHz.

(e) Each transmitter in the MICS service must maintain a frequency stability of +/- 100 ppm of the operating frequency over the range:

(1) 25°C to 45°C in the case of medical implant transmitters; and

(2) 0°C to 55°C in the case of medical implant programmer/control transmitters.

(f) The provisions of this section shall not be used to extend the range of spectrum occupied over space or time for the purpose denying fair access to spectrum for other MICS systems.

12. Section 95.631 is amended by adding paragraph (i) to read as follows:

**§ 95.631 Emission types.**

\* \* \* \* \*

(i) A MICS station may transmit any emission type appropriate for communications in this service. Voice communications, however, are prohibited.

13. Section 95.633 is amended by adding paragraph (f) to read as follows:

**§ 95.633 Emission bandwidth.**

\* \* \* \* \*

(f) For transmitters in the MICS:

(1) The maximum authorized emission bandwidth is 300 kHz.

(2) Lesser authorized emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635 and that the power radiated in any 300 kHz bandwidth does not exceed 25 microwatts EIRP. See §§ 95.605 and 95.639(g) regarding power measurement procedures.

(3) Emission bandwidth will be determined by measuring the width of the signal between two points, one below the carrier center frequency and one above the carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier. Compliance with the emission bandwidth limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

14. Section 95.635 is amended by revising paragraph (b) and adding paragraph (e) to read as follows:

**§ 95.635 Unwanted radiation.**

\* \* \* \* \*

(b) The power of each unwanted emission shall be less than TP as specified in the applicable paragraphs listed in the following table:

Transmitter	Emission type	Applicable subparagraphs
GMRS.....	A1D, A3E, F1D, G1D, F3E, G3E with filtering .....	(1), (3), (7)
	A1D, A3E, F1D, G1D, F3E, G3E without filtering .	(5), (6), (7)
	H1D, J1D, R1D, H3E, J3E, R3E .....	(2), (4), (7)
FRS.....	F3E with filtering .....	(1), (3), (7)
R/C:		
27 MHz .....	As specified in § 95.631(b) .....	(1), (3), (7)
72-76 MHz ..	As specified in § 95.631(b) .....	(1), (3), (7), (10),
		(11), (12)
CB .....	A1D, A3E .....	(1), (3), (8), (9)
	H1D, J1D, R1D, H3E, J3E, R3E .....	(2), (4), (8), (9)
	A1D, A3E type accepted before September 10, 1976	(1), (3), (7)
	H1D, J1D, R1D, H3E, J3E, R3E type accepted	
	before September 10, 1986 .....	(2), (4), (7)
LPRS .....	As specified in paragraph (c)	
MICS .....	As specified in paragraph (d)	

NOTE 1 - Filtering noted for GMRS and FRS transmitters refers to the requirement in § 95.637(b).

NOTE 2 - Unwanted R radiation may be stated in mean power or in peak envelope power, provided it is stated in the same parameter as T.

NOTE 3 - Subparagraphs (1), (10), (11), and (12) of this paragraph apply to transmitters operating in the 72-76 MHz band that are manufactured or imported into the United States on or after March 1, 1992, or marketed or sold on or after March 1, 1993. Subparagraphs (1), (3), and (7) of this paragraph apply to transmitters operating in the 72-76 MHz band manufactured or imported into the United States before March 1, 1992, or marketed before March 1, 1993.

NOTE 4 - If spurious or harmonic emissions result in *harmful interference* (any transmission, radiation or induction that endangers the functioning of a radionavigation or other safety service or seriously degrades, obstructs or repeatedly interrupts a radiocommunication service operating in accordance with applicable laws, treaties and regulations), the FCC may, at its discretion, require appropriate technical changes in the station equipment to alleviate the interference, including the use of a low pass filter between the transmitter antenna terminals and the antenna feed line.

(1) At least 25 dB (decibels) on any frequency removed from the center of the authorized bandwidth by more than 50% up to and including 100% of the authorized bandwidth.

(2) At least 25 dB on any frequency removed from the center of the authorized bandwidth by more than 50% up to and including 150% of the authorized bandwidth.

(3) At least 35 dB on any frequency removed from the center of the authorized bandwidth by more than 100% up to and including 250% of the authorized bandwidth.

(4) At least 35 dB on any frequency removed from the center of the authorized bandwidth by more than 150% up to and including 250% of the authorized bandwidth.

(5) At least  $83 \log_{10} (f_d/5)$  dB on any frequency removed from the center of the authorized bandwidth by a displacement frequency ( $f_d$  in kHz), of more than 5 kHz up to and including 10 kHz.

(6) At least  $116 \log_{10} (f_d/6.1)$  dB, or if less  $50 + 10 \log_{10} (T)$  dB, on any frequency removed from the center of the authorized bandwidth by a displacement frequency ( $f_d$  in kHz), of more than 10 kHz up to and including 250% of the authorized bandwidth.

(7) At least  $43 + 10 \log_{10} (T)$  dB on any frequency removed from the center of the authorized bandwidth by more than 250%.

(8) At least  $53 + 10 \log_{10} (T)$  dB on any frequency removed from the center of the authorized bandwidth by more than 250%.

(9) At least 60 dB on any frequency twice or greater than twice the fundamental frequency.

(10) At least 45 dB on any frequency removed from the center of the authorized bandwidth by more than 100% up to and including 125% of the authorized bandwidth.

(11) At least 55 dB on any frequency removed from the center of the authorized bandwidth by more than 125% up to and including 250% of the authorized bandwidth.

(12) At least  $56 + 10 \log_{10} (T)$  dB on any frequency removed from the center of the authorized bandwidth by more than 250%.

\* \* \* \* \*

(e) For transmitters designed to operate in the MICS, emissions shall be attenuated in accordance with the following:

(1) Emissions more than 250 kHz outside of the MICS band (402.000 MHz - 405.000 MHz) shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength ( $\mu\text{V}/\text{m}$ )	Measurement distance (m)
30-88	100	3
88-216	150	3
216-960	200	3
960 and above	500	3

NOTE - At band edges, the tighter limit applies.

(2) The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. See also § 95.605.

(3) The emissions from a MICS transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

(4) Emissions within the MICS band (402-405 MHz) more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy, will be attenuated below the transmitter output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

(5) Emissions 250 kHz or less that are above and below the MICS band (402-405 MHz) will be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

15. Section 95.639 is amended by adding paragraph (g) to read as follows:

**§ 95.639 Maximum transmitter power.**

\* \* \* \* \*

(g) In the MICS the following limits apply:

(1) The maximum EIRP for MICS transmitter stations is 25 microwatts. The antenna associated with any MICS transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance of any MICS transmitter with the 25 microwatts EIRP limit 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 EIRP is 18.2 mV/meter when measured on an open area test site, or 9.1 mV/meter when measured on a test site equivalent to free space such as a fully anechoic test chamber. In either

case, compliance is 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, instrumentation techniques set forth in ANSI C63.17-1998, Section 6.1.2.2.1 or Section 6.1.2.2.2 may be used in determining compliance with the above specifications.

(2) For a transmitter intended to be implanted in a human body, the following test fixture must be used to simulate operation of the implant under actual operating conditions. See § 95.605.

(i) For measurement purposes to determine compliance with emission limits, the radiating characteristics of an implant transmitter placed in a test fixture should approximate those of an implant transmitter placed in a human body. An appropriate human torso simulator for testing medical implant transmitters consists of a cylindrical Plexiglas container with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm. It must be completely filled with a material that is sufficiently fluidic that it will flow around the implant without any voids. The dielectric and conductivity properties of this material must match the dielectric and conductivity properties of human muscle tissue at 403.5 MHz. All emissions measurements will be made using the above specification at a nominal temperature of 20-25°C. Simple saline solutions do not meet the above criteria. A mounting grid for the implant inside the container must be provided that permits the radiating element or elements of the implant to be positioned vertically and horizontally. The grid should also support any additional implant leads associated with the therapeutic function in a fixed repeatable manner. The implant must be mounted 6 cm from the sidewall and centered vertically within the container. The above fixture shall be placed on a turntable such that the implant transmitter will be located at a nominal 1.5-meter height above ground and at a 3-meter distance from the measurement antenna. Radiated emissions measurements shall then be performed to insure compliance with the applicable technical specifications.

(ii) A formula for a suitable tissue substitute material is defined in the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in "Bioelectromagnetics 8:29-36 (1987)".

(3) The power radiated in any 300 kHz bandwidth shall not exceed 25 microwatts EIRP. See §§ 95.633(e) and 95.639(g).

16. Section 95.649 is amended by revising the text to read as follows:

**§ 95.649 Power capability.**

No FRS, R/C, CB, LPRS, MURS or MICS transmitter shall incorporate provisions for increasing its transmitter power to any level in excess of the limits specified in § 95.639.

17. Section 95.651 is amended by revising the text to read as follows:

**§ 95.651 Crystal control required.**

All transmitters used in the Personal Radio Services must be crystal controlled, except an R/C station that transmits in the 26-27 MHz frequency band, a FRS unit, a LPRS unit, a MURS unit or a MICS transmitter.

18. APPENDIX 1 TO SUBPART E TO PART 95 - GLOSSARY OF TERMS is revised to read as follows:

The definitions used in part 95, Subpart E are:

*Authorized bandwidth.* Maximum permissible bandwidth of a transmission.

*Carrier power.* Average TP during one unmodulated RF cycle.

*CB.* Citizens Band Radio Service.

*CB transmitter.* A transmitter that operates or is intended to operate at a station authorized in the CB.

*Channel frequencies.* Reference frequencies from which the carrier frequency, suppressed or otherwise, may not deviate by more than the specified frequency tolerance.

*Crystal.* Quartz piezo-electric element.

*Crystal controlled.* Use of a crystal to establish the transmitted frequency.

*dB.* Decibels.

*EIRP.* Effective Isotropic Radiated Power. Antenna input power times gain for free-space or in-tissue measurement configurations required by MICS, expressed in watts, where the gain is referenced to an isotropic radiator.

*FCC.* Federal Communications Commission.

*Filtering.* Refers to the requirement in § 95.633(b).

*FRS.* Family Radio Service.

*GMRS.* General Mobile Radio Service.

*GMRS transmitter.* A transmitter that operates or is intended to operate at a station authorized in the GMRS.

*Harmful interference.* Any transmission, radiation or induction that endangers the functioning of a radionavigation or other safety service or seriously degrades, obstructs or repeatedly interrupts a radiocommunication service operating in accordance with applicable laws, treaties and regulations.

*Mean power.* TP averaged over at least 30 cycles of the lowest modulating frequency, typically 0.1 seconds at maximum power.

*MICS.* Medical Implant Communications Service.

*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 Communications Service (MICS) transmitter.* A transmitter authorized to operated in the MICS.

*Medical implant programmer/control transmitter.* A MICS transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver connected to a medical implant device.

*Medical implant transmitter.* A MICS transmitter that operates or is designed to operate within a human body for the purpose of facilitating communications from a medical implant device.

*Peak envelope power.* TP averaged during one RF cycle at the highest crest of the modulation envelope.

*R/C.* Radio Control Radio Service.

*R/C transmitter.* A transmitter that operates or is intended to operate at a station authorized in the R/C.

*RF.* Radio frequency.

*Transmitter.* Apparatus that converts electrical energy received from a source into RF energy capable of being radiated.

*TP.* RF transmitter power expressed in W, either mean or peak envelope, as measured at the transmitter output antenna terminals.

*W.* Watts.

19. Section 95.1019 is revised to read as follows:

**§ 95.1019 Marketing limitations.**

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

20. Subpart I is added to read as follows:

**Subpart I - Medical Implant Communications Service (MICS)**

**§ 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.**

MICS stations may transmit non-voice data as permitted below:

(a) Except as provided below and 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 external to the body in which the medical implant transmitter is implanted or is to be implanted.

(c) Medical implant programmer/control transmitters may be interconnected with other telecommunications systems including the public switched telephone network.

(d) Medical implant programmer/control transmitters may transmit during a MICS communications session, as defined in Section 95.628, for the purpose of facilitating MICS system operation for no more than 5 seconds without the communications of data.

(e) Medical implant programmer/control transmitters may not be used to relay information to a receiver that is not included with a medical implant device. Wireless retransmission of information intended to be transmitted by a medical implant programmer/control transmitter or information received from a medical implant transmitter shall be conducted using other radio services that operate in spectrum outside of the MICS band.

**§ 95.1211 Channel use policy.**

(a) The channels authorized for MICS operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.

(b) Those using MICS transmitters must cooperate in the selection and use of channels in order to reduce interference and make the most effective use of the authorized facilities. Channels must be selected in an effort to avoid interference to other MICS transmissions. See § 95.628.

(c) Operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services. MICS stations must accept any interference from stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services.

**§ 95.1213 Antennas.**

No antenna for a medical implant programmer/control transmitter shall be configured for permanent outdoor use, provided, however, that any antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.

**§ 95.1215 Disclosure policies**

(a) Manufacturers of MICS transmitters must include with each transmitting device the following statement: "This transmitter is authorized by rule under the Medical Implant Communications Service (47 C.F.R. Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."

**§ 95.1217 Labeling requirements.**

(a) Medical implant programmer/controller transmitters shall be labeled as provided in Part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

This device may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

(b) Where a medical implant programmer/control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.

(c) Medical implant transmitters shall be identified with a serial number. The FCC ID number associated with the transmitter and the information required by Section 2.925 of the FCC Rules may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.

**§ 95.1219 Marketing limitations.**

Transmitters intended for operation in the MICS may be marketed and sold only for those uses described in § 95.1209 of this part.