

FCC MAIL SECTION

Federal Communications Commission

FCC 99-23

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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 No. 9157  
 To Establish a Medical Implant )  
 Communications Service in the )  
 402-405 MHz Band )

## NOTICE OF PROPOSED RULE MAKING

Adopted: February 12, 1999

Released: February 24, 1999

Comment date: April 9, 1999

Reply comment date: April 26, 1999

By the Commission:

## I. INTRODUCTION AND EXECUTIVE SUMMARY

1. On July 28, 1997, Medtronic, Inc. ("Medtronic") filed a Petition for Rule Making ("Petition"), requesting amendment of Parts 2 and 95 of the Commission's Rules to establish a Medical Implant Communications Service ("MICS") in the 402-405 MHz band.<sup>1</sup> MICS operations would consist of high-speed, ultra low power, non-voice transmissions to and from implanted medical devices such as cardiac pacemakers and defibrillators. In view of the potential public health benefits engendered by Medtronic's proposal, this *Notice of Proposed Rule Making* ("Notice") proposes to: (1) amend the Table of Frequency Allocations in Section 2.106 of the Commission's Rules, 47 C.F.R. § 2.106, to allocate the 402-405 MHz band to the mobile service on a shared basis and designate this allocation for use by the MICS; and (2) amend Part 95 of the Commission's Rules, 47 C.F.R. Part 95, as necessary, to codify service rules for the MICS.

<sup>1</sup> The Petition was assigned RM-9157, and placed on Public Notice, Report No. 2220 (August 27, 1997). Comments were received from six parties -- David Steinhaus, M.D. of Cardiovascular Consultants, W. Ben Johnson, M.D. of the Iowa Heart Center, Marshall S. Stanton, M.D. of the Mayo Clinic, George J. Klein, M.D. of the University of Western Ontario, Edward V. Platia, M.D. of the Washington Hospital Center, and Douglas P. Zipes, M.D. of the Indiana University School of Medicine. All of the commenters support the Petition. In general, the comments did not discuss specifics of a MICS, but rather described the benefits the commenters believed would result from establishing a MICS. Reply comments were received from Medtronic. Because the 402-405 MHz band is shared with the Federal Government, the Petition was submitted to the Interdepartment Radio Advisory Committee (IRAC) for review. It was approved by the IRAC without objection on March 10, 1998.

## II. DISCUSSION

2. As this Commission performs its core spectrum management function, it must be acutely attuned to the public interest, including matters of public health and safety. Medical implant devices help to promote the health and well-being of a great number of Americans by improving the length and quality of their lives. For example, medical implant devices regulate heart rates by means of pacing and/or defibrillation, control pain, improve motor functions, treat neurological tremors, administer medication, and control incontinence. It is estimated that in the United States, at least 75,000 pacemakers are implanted in new patients each year. Other types of medical implant devices also perform an expanding variety of diagnostic and therapeutic functions that benefit millions of people worldwide.

3. In its Petition, Medtronic states that medical implant devices allow physicians to, among other things, adjust the parameters of the device (*e.g.*, pacing rate), retrieve information stored within the device (*e.g.*, electrocardiograms), and monitor real-time transmissions of vital information for short periods of time (*e.g.*, cardiac performance during the implant procedure).<sup>2</sup> Medtronic further states that despite these significant benefits, there are two notable technical limitations with currently available devices that prevent them from providing even greater benefits to patients. First, as described below, current devices use magnetically coupled coils and a programming head to establish a communications link.<sup>3</sup> Second, the devices now operate at a frequency of 175 kHz, and transfer data at a rate of only about two kilobits per second which requires interrogation periods of up to 15 minutes. According to Medtronic, these periods are likely to increase to hours due to the expansion in data capacity expected in the near future, thus making the interrogation periods unmanageably long.<sup>4</sup>

4. Current medical implants also pose certain challenges during the surgery to implant the medical device. For instance, the physician must precisely position a programming head over the open incision into which the device has just been placed, which increases the risk of infection. Any movement by the patient can break the communications link during the transmission of vital data, potentially delaying the completion of the surgery. In addition, the cord linking the programming head to the associated reader limits the mobility of medical personnel and equipment.

5. The current technology also poses some limitations for medical personnel and patients post-surgery. For example, after surgery, the programming head must be placed directly on the skin of the patient as close as possible to the implanted device in order to establish a communications link with the device and to prevent any corruption or break in the link caused by the patient's movement. Weak or elderly patients often are unable to hold the heavy programming head over the implant area without moving for a sufficient period of time to establish and maintain a good communications link. For this reason, the data obtained from home monitoring is often unreliable.<sup>5</sup>

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<sup>2</sup> *Id.* at 3.

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

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 3, 4.

*Establishing a MICS*

6. Medtronic contends that the current inductively coupled medical implant devices are inefficient in operation and cumbersome to the patient. A new generation of implant devices has been developed that would provide a safer, less expensive, and less invasive method to diagnose and manage patient conditions than the inductive systems now used.<sup>6</sup> Medtronic further contends that a communications system that would allow physicians or patients to establish and maintain a painless and sterile communications link would benefit the public interest and significantly lower health care costs.<sup>7</sup> For example, the MICS would allow the use of implantable hemodynamic monitors ("IHMs") to measure physiologic parameters within the body, such as cardiac output, thus replacing the need for dangerous and expensive catheterizations. Improvements in medical implant technology are constantly being made and new medical implant devices are being developed to help an increasing number of patients with a wide range of medical problems, including atrial fibrillation, congestive heart failure, Parkinson's disease and cerebral palsy.<sup>8</sup> Medtronic, therefore, requests that the Commission establish the MICS as an ultra low power, unlicensed mobile radio service, operating in the 402-405 MHz band,<sup>9</sup> for transmitting data in support of the diagnostic and/or therapeutic functions associated with medical implant devices.

7. We tentatively conclude that establishing the MICS would further the public interest by promoting a significant advancement in communications with implanted medical devices in a manner that would be far more efficient than now experienced in current systems. We believe that the MICS would greatly improve the utility of medical implant devices by allowing physicians to establish high speed, easy-to-use, reliable, short-range, wireless links to interconnect the implanted medical devices with monitoring equipment. The two key attributes of the MICS that would enable this improvement are an operating range of approximately two meters and a 100 kilobit per second data transmission rate. This higher data exchange rate also would allow communications to keep pace with the rapidly increasing information storage capabilities of medical implant devices. We also anticipate that medical implant devices developed under the MICS would provide a safer, less expensive, and less invasive<sup>10</sup> method to diagnose and manage patient conditions than the inductive systems now used. Thus, we propose to amend Part 95 of the Commission's Rules to establish the MICS. We further propose that the MICS be used for transmitting data in support of the diagnostic and/or therapeutic functions associated with medical implant devices. We seek comment on our proposal.

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<sup>6</sup> *Id.* at 1.

<sup>7</sup> *Id.*

<sup>8</sup> Petition at 2.

<sup>9</sup> The 402-405 MHz band is part of the 400-406 MHz Meteorological Aids Service ("Met aids") band. See § 2.106, Table of Frequency Allocations. Users of the Met aids band employ meteorological devices such as radiosondes, rocketsondes, and wind profiling radar systems. According to Medtronic, MICS operations and technologies require three megahertz of continuous bandwidth, and minimum interference to Met aids operations would result by using the 402-405 MHz portion of the Met aids band. See Petition at 1, 14.

<sup>10</sup> MICS devices would be less invasive to a patient's privacy because they need not disrobe during examinations or treatments and also would not be touched by medical personnel. The faster data transfer rates would also mean less diagnostic and treatment time.

*Technical Considerations*

8. Spectrum. The Commission has made other spectrum available for use by physicians and health care providers in Part 15 of the Commission's Rules.<sup>11</sup> With respect to spectrum available under Part 15, Medtronic states that technical considerations make that spectrum ill-suited for proposed MICS operations because both the 174-216 MHz and the 512-566 MHz bands are outside the range of spectrum it considers most suitable for propagation of radio signals within the human body.<sup>12</sup> Medtronic further states that medical devices operating in either of those bands must share that spectrum with high power adjacent broadcasting stations which might cause interference, and that neither band lends itself to international compatibility, as does the 402-405 MHz band.<sup>13</sup> Medtronic contends that with respect to available licensed spectrum under Part 90 of the Commission's Rules, MICS operations also would be impractical because of similar technical considerations.<sup>14</sup> Although Part 90 permits operation of biomedical telemetry devices in the 450-470 MHz band,<sup>15</sup> Medtronic argues that the 450-470 MHz band also is outside the preferred range of spectrum for propagation of radio signals within the human body, and that the 450-470 MHz band is populated by relatively high-powered transmitters. Consequently, Medtronic contends that operation under Part 90 is not a viable alternative for MICS operations, stating that MICS operation at power levels that would be necessary to overcome interference from other medical devices under Part 90 could result in harmful interference to other devices sharing the frequency band.<sup>16</sup>

9. Medtronic contends that the 402-405 MHz band, besides being the frequency band it believes most desirable for MICS operations, appears to be the only suitable spectrum that can support three megahertz of bandwidth for MICS worldwide.<sup>17</sup> According to Medtronic, some nations may be unable to allocate, even on a secondary basis, the entire 402-405 MHz band. However, the use of at least a portion of this band will mean that U.S. travelers abroad will have a high probability of successful MICS

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<sup>11</sup> Part 15 of the Commission's Rules 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.

<sup>12</sup> Petition at 7-12. In an *ex parte* submission, Medtronic states that the appropriateness of the 402-405 MHz band for MICS operations is a result of a combination of factors and is not solely dependent on the transmission characteristics of the band. Medtronic claims that if only propagation through tissue were concerned, the most desirable frequencies would be below the 402-405 MHz band. However, other constraints such as the physical size and power consumption of medical implant transceivers, a relatively noise free radio environment, and international frequency compatibility also affect the choice of spectrum. These factors, coupled with the good tissue propagation characteristics of the 402-405 MHz band make it the most desirable band for use in the MICS. See letter from David E. Hilliard, Counsel for Medtronic, Inc., to Eugene Thomson, Public Safety and Private Wireless Division, Wireless Telecommunications Bureau, dated June 8, 1998.

<sup>13</sup> Petition at 11.

<sup>14</sup> *Id.*

<sup>15</sup> See 47 C.F.R. §§ 90.20, 90.238, and 90.267.

<sup>16</sup> Petition at 11-12.

<sup>17</sup> *Id.* at 12.

operation.<sup>18</sup> Conversely, Medtronic points out that foreign visitors to the United States with MICS implants will not have to forego use of potentially life-saving technology.<sup>19</sup> Medtronic asserts that after careful analyses of these requirements and international regulations, it has determined that use of the 402-405 MHz band appears to be the only viable spectrum option for effective MICS operations.<sup>20</sup> Medtronic further asserts that MICS can be implemented in the 402-405 MHz band without interference to Metaids operations,<sup>21</sup> citing an International Telecommunication Union (ITU) recommendation that indicated that sharing is feasible between the MICS and Metaids Systems operating in the 401-406 MHz band if the effective isotropic radiated power ("EIRP") of MICS transmitters is limited to 25 microwatts.<sup>22</sup> Medtronic states that because of the very low power and duty cycle of MICS transmitters, there is virtually no threat of interference to any part of the extensive Metaids infrastructure, including but not limited to the measurement and transmission of meteorological information and wind profiling radar systems. With respect to interference from Metaids systems<sup>23</sup> to the MICS, Medtronic states that although the primary users of the Metaids band could cause interference to the MICS, the potential for a radiosonde system to interfere with MICS is small because of the ten-channel capability of the MICS. In addition, wind profiling radar systems are generally geographically remote to MICS locations and have very directive antenna patterns, all to the advantage of MICS operations.<sup>24</sup> Therefore, Medtronic suggests that the MICS be designated as a secondary use of the 402-405 MHz part of the Metaids band.<sup>25</sup>

10. Bandwidth. Medtronic states that the bandwidth requirements of MICS devices are determined by three factors: rate of data transmission, channelization, and receiver frequency accuracy.<sup>26</sup> Medtronic claims that in order to support a 100 kilobits per second uplink (implant to programmer unit) data rate using frequency shift keyed (FSK) modulation, the uplink bandwidth must be approximately 300 kHz.<sup>27</sup> With a total of three megahertz of spectrum available, the MICS will be able to support ten individual 300 kHz channels. Ten available channels will greatly reduce the possibility of multiple programmer units in the same area interfering with each other, will allow the system to avoid interference from other radio frequency devices that are used in clinical environments, and will help to protect patients

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<sup>18</sup> *Id.*

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

<sup>20</sup> *Id.* at 7, 8.

<sup>21</sup> *Id.*, at 12, 14. *See also* n. 9.

<sup>22</sup> In its Petition, 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).

<sup>23</sup> *See* n.9, *supra*.

*See also* n. 34 *infra*. <sup>24</sup> *See* Petition at 13.

<sup>25</sup> *See* Petition at 2. *See also* n. 34 *infra*.

<sup>26</sup> Petition at 10.

<sup>27</sup> *Id.*

from any jamming or data corruption occurring as a result of another device being within range of the implant.<sup>28</sup> We believe that the potential for interference between multiple MICS systems operating in the same area must be minimized to prevent adverse effects on patients. After considering Medtronic's arguments, we conclude that a 300 kHz bandwidth is necessary to support the required data rate transmission. The three MHz of spectrum that would be made available in the 402-405 MHz band would provide for ten 300 kHz channels and, with multiple channel availability, interference between MICS systems operating in the same area, or from other medical devices, would be minimized. We, therefore, propose that the maximum channelization for MICS equipment be 300 kHz. We invite comments on this proposal.

11. Transmitter Power. Medtronic states that the required maximum EIRP for programmer/control stations in the MICS is 25 microwatts, and that the maximum field strength from an implanted transmitter should be limited to 9.1 mV/m (rms) at 3 meters, as measured with an instrument having a peak detector function.<sup>29</sup> Additionally, Medtronic suggests that the average power radiated in any 300 kHz bandwidth should be required not to exceed 25 microwatts EIRP.<sup>30</sup> Medtronic has suggested these values for transmitter power that we propose to adopt. We also ask for comments on these values.

12. Miscellaneous Technical Standards. Additionally, we propose other technical standards, as submitted by Medtronic in its Petition, concerning transmitter frequency stability, emission types, unwanted emissions, and MICS transmitter certification requirements. Comments are requested on all proposed rules as contained in Appendix B.

13. Exposure to Radiofrequency Fields. Some concern has been expressed as to exposure of patients or medical practitioners to radio frequency (RF) emissions from devices that would operate in the proposed service. The Commission has adopted guidelines for human exposure to RF electromagnetic fields.<sup>31</sup> The values for Maximum Permissible Exposure (MPE) adopted by the FCC for the 402-405 MHz frequency band range from 0.27 milliwatts per squared centimeter (mW/cm<sup>2</sup>) for general population/uncontrolled exposures to 1.34 mW/cm<sup>2</sup> for occupational/controlled exposures. Exposures are averaged over either 30 minutes (general population/uncontrolled exposures) or 6 minutes (occupational/controlled exposures). Since the proposed EIRP level, 25 microwatts, is very low, it is extremely unlikely that either patients or medical professionals could be exposed in excess of either the general population/uncontrolled or occupational/controlled limits. For these reasons we propose to categorically exclude this service from requirements for routine evaluation of human exposure to RF emissions as is allowed under our rules.<sup>32</sup> We invite comment on this proposal.

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<sup>28</sup> Computers and other RF generating devices are routinely used in hospitals, which complicates the maintenance of electromagnetic compatibility at system levels because of the RF noise generated by these devices. See Petition at n.8 and Appendix B.

<sup>29</sup> See proposed § 95.605 concerning measurement procedures in Appendix B.

<sup>30</sup> See proposed § 95.633(e)(2) in Appendix B.

<sup>31</sup> See 47 CFR 1.1307(b) and 1.1310.

<sup>32</sup> See 47 CFR 1.1307(b)(1).

*Administration of the MICS*

14. In the Petition, Medtronic suggests that the MICS be licensed by rule without individual station licenses.<sup>33</sup> We agree. For the MICS to be attractive to users, there should be no requirement for a station license. We believe that the administrative burdens associated with the individual licensing of MICS operations would outweigh any potential benefits from such licensing. Moreover, several categories of products, including equipment operating under Part 15 and some transmission systems operating under Part 95, do not require a station license. We do not believe any regulatory purpose would be served by requiring station licenses in such a radio service. After analysis of the record, we propose to allocate the 402-405 MHz band to the mobile service and designate the allocation for MICS operations on a shared, non-interference basis.<sup>34</sup> We also propose to establish the MICS within the Citizens Band (CB) Radio Service under Part 95 of the Commission's Rules.<sup>35</sup> We further propose to authorize operation by rule pursuant to Section 307(e) of the Communications Act<sup>36</sup> and to regulate the usage of the MICS units through the technical standards and certification requirements set forth in Appendix B. We specifically solicit comments regarding the proposed allocation and sufficiency of the proposed technical standards to support this new radio service.

**III. CONCLUSION**

15. We conclude that the Commission should 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 the Commission's equipment authorization program. Therefore, this *Notice* proposes specific operational and technical standards for the MICS that will ensure that neither Metacids nor MICS operations will experience any interference from sharing the 402-405 MHz band.

16. For the foregoing reasons, we adopt this *Notice* and propose to: (1) amend the Table of Allocations at Section 2.106 of the Commission's Rules to allocate the 402-405 MHz band to the mobile service and designate the MICS as a shared operation in the band and; (2) revise Part 95 of the Commission's Rules to permit the operation of ultra low power MICS transmitters in the 402-405 MHz

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<sup>33</sup> Petition at i and 2.

<sup>34</sup> In the Petition, Medtronic suggested that MICS be designated for operation in the 402-405 MHz band on a secondary basis. The intent of this request was to require the MICS to operate on a non-interference basis in the 402-405 MHz band. Operations under Part 95 are not designated as primary or secondary in 47 C.F.R. Part 95. Therefore, we are proposing a footnote, NG 156, to the Table of Frequency Allocations in 47 C.F.R. § 2.106 which states that MICS stations cannot cause interference to any other stations in the 402-405 MHz band.

<sup>35</sup> The Commission has previously taken similar action when it included the Family Radio Service and the Low Power Radio Service in the Citizens Band Radio Services. See 47 C.F.R. §§ 95.401 (b) and 95.401(c). See also, 11 FCC Rcd 12977 (1996) and 11 FCC Rcd 18517 (1996).

<sup>36</sup> Section 307(e)(3) of the Communications Act of 1934, as amended, 47 U.S.C. § 307(e)(3), ("Act"), provides that the term "citizens band radio service" shall have the meaning given it by the Commission by rule. Section 307(e)(1) of the Act provides that if the Commission determines that if 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.

band without an individual license issued by the Commission. We believe that the proposed rules will allow use of newly-developed, life-saving medical technology without harming other users of the frequency band.

#### IV. PROCEDURAL MATTERS

##### ***Ex Parte* Rules - Permit-But-Disclose Proceeding**

17. This is a permit-but-disclose notice and comment rule making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's Rules. See generally 47 C.F.R. §§ 1.1200(a), 1.1203, and 1.1206.

##### **Regulatory Flexibility Act**

18. With respect to this *Notice*, an Initial Regulatory Flexibility Analysis ("IRFA") is contained in Appendix A. As required by the Regulatory Flexibility Act,<sup>37</sup> the Commission has prepared an IRFA of the expected significant economic impact on small entities by the policies and rules proposed in this *Notice*. Written public comments are requested on the IRFA. We ask questions in the IRFA regarding the prevalence of small businesses in the industries covered by this *Notice*. Comments on the IRFA must be filed in accordance with the same filing deadlines as comments on the *Notice* and must have a distinct heading designating them as responses to the IRFA.

##### **Comment Submission**

19. Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 C.F.R. §§ 1.415, 1.419, interested parties may file comments on before April 9, 1999, and reply comments on or before April 26, 1999. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 Fed. Reg. 24,121 (1998).

20. Comments filed through the ECFS can be sent as an electronic file via the Internet to <<http://www.fcc.gov/e-file/ecfs.html>>. Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to [ecfs@fcc.gov](mailto:ecfs@fcc.gov), and should include the following words in the body of the message, "get form <your e-mail address>." A sample form and directions will be sent in reply.

21. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appear in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary, Federal Communications Commission, The Portals, 445 Twelfth St. S.W., Room TW-A325, Washington, D.C. 20554.

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<sup>37</sup> Pub. L. No. 96-354, 94 Stat. 1164, 5 U.S.C. § 601 *et seq.* (1981), as amended.

22. Alternative formats (computer diskette, large print, audio cassette and Braille) 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 *Notice* can also be downloaded at <http://www.fcc.gov/df/>.

23. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center of the Federal Communications Commission, 1919 M Street, N.W., Room 239, Washington, D. C.

#### **Paperwork Reduction Act of 1995 Analysis**

24. This *Notice* has been analyzed with respect to the Paperwork Reduction Act of 1995, Pub .L. No. 104-13, and found to impose no new or modified information collection requirements on the public.

#### **V. ORDERING CLAUSES**

25. Accordingly, IT IS ORDERED that, pursuant to Sections 4(i), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), and 303(r), notice is hereby given of proposed amendments to Parts 2 and 95 of the Commission's Rules, 47 C.F.R. Parts 2 and 95, in accordance with the proposals, discussions, and statement of issues in this *Notice of Proposed Rule Making*.

26. IT IS FURTHER ORDERED that the Commission's Office of Public Affairs, Reference Operations Division, SHALL SEND a copy of this *Notice of Proposed Rule Making*, including the Initial Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

#### **Further Information**

27. For further information, contact Gene Thomson, Policy and Rules Branch, Public Safety and Private Wireless Division, Wireless Telecommunications Bureau, (202) 418-0680.

FEDERAL COMMUNICATIONS COMMISSION



Magalie Roman Salas  
Secretary

Attachments: Appendices

## APPENDIX A

**Initial Regulatory Flexibility Analysis**

As required by the Regulatory Flexibility Act ("RFA"),<sup>38</sup> the Commission has prepared this present Initial Regulatory Flexibility Analysis ("IRFA") of the possible significant economic impact on small entities by the policies and rules proposed in this *Notice of Proposed Rule Making* ("*Notice*"). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on this *Notice* provided above in paragraph 20. The Commission will send a copy of the *Notice*, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. See 5 U.S.C. § 603(a). In addition, the *Notice* and IRFA will be published in the Federal Register. See *id.*

**A. Need for, and Objectives of, the Proposed Rules:**

1. In this proceeding, the Commission proposes to amend Parts 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 proposed rules would allow use of newly-developed, life-saving medical technology without harming other users of the applicable frequency bands.

**B. Legal Basis:**

2. Authority for issuance of this *Notice of Proposed Rule Making* is contained in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i) and 303(r).

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

3. The proposed rules apply to manufacturers of medical implant devices and users of the proposed MICS equipment, such as hospitals and clinics. The RFA also includes small governmental entities as a part of the regulatory flexibility analysis.<sup>39</sup> The definition of a small governmental entity is one with a population of less than 50,000.<sup>40</sup> There are 85,006 governmental entities in the nation.<sup>41</sup> This number includes such entities as states, counties, cities, utility districts, and school districts. There are no figures available on what portion of this number has populations of fewer than 50,000. However, this number includes 38,978 counties, cities, and towns, and of those, 37,566, or 96 percent, have populations

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<sup>38</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. 104-12, 110 Stat. 848 (1996) ("CWAAA"). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 ("SBREFA").

<sup>39</sup> See 5 U.S.C. § 601(5) (including cities, counties, towns, townships, villages, school districts, or special districts).

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

<sup>41</sup> 1992 Census of Governments, U.S. Bureau of the Census, U.S. Department of Commerce.

of fewer than 50,000.<sup>42</sup> The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Of the estimated 85,006 governmental entities, many are hospitals and health care facilities. We ask for comments on what percentage of local government health care facilities are small entities that may be affected by the proposed rules.

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

4. No reporting or recordkeeping requirements would be imposed as a result of the actions proposed in this rule making proceeding. Manufacturers of medical implant transmitters would be required to follow the Commission's normal equipment authorization procedures.

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

5. By making frequency spectrum available, the proposed rules could have a beneficial economic impact on those small business entities that would either manufacture, or contribute to the manufacturing of equipment used in the Medical Implant Communications Service. Individuals who are the recipients of implanted MICS devices would be the greatest beneficiaries economically. 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 5%, the savings would be nearly \$2B per year. We seek comment on our tentative conclusions.

**F. Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rules:**

6. None.

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<sup>42</sup> *Id.*

**APPENDIX B - PROPOSED RULES**

Parts 2 and 95 of Title 47 of the Code of Federal Regulations are proposed to be amended as follows:

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

1. The authority citation for Part 2 continues to read as follows:

**Authority:** 47 U.S.C. 154, 302, 303, 307 and 336, unless otherwise noted.

2. In Section 2.106, the Table of Frequency Allocations is amended by revising the entries for the 402-403 and 403-406 MHz bands by adding the Medical Implant Communications Service (MICS) in the Non-Government 402-403 MHz and 403-406 MHz bands, and adding Non-Government footnote NG156 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                    | ***                        |                            | 402-403<br>*****    | 402-403<br>*****<br>Mobile<br>US70 NG156 | PERSONAL (95)       | 402-403<br>Medical<br>Implant<br>Communications (MICS) |
| 403-406                    | ***                        |                            | 403-406<br>*****    | 403-406<br>*****<br>Mobile<br>US70 NG156 | PERSONAL (95)       | 403-406<br>Medical<br>Implant<br>Communications (MICS) |

\* \* \* \* \*

NG156 Medical Implant Communications Service (MICS) stations are authorized by rule on the conditions 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 95.1115 of this Chapter.

3. 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**

4. 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.**

5. Section 95.401 is amended by adding paragraph (d) 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 H of this part.

6. 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, and the Medical Implant Communications Service (MICS)--subpart H.

7. Section 95.603 is amended by adding paragraph (f) to read as follows:

**§ 95.603 Certification required.**

\* \* \* \* \*

(f) 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.

8. 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 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 the tissue in which the transmitter is to be implanted. Frequency stability testing for MICS transmitters shall be performed over the temperature range set forth in § 95.630.

\* \* \* \* \*

9. Section 96.630 is added to read as follows:

**§ 95.630 MICS Transmitter frequencies and stability.**

(a) 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 the requirements of § 95.635.

(b) The authorized bandwidth of the emission from a MICS station shall not exceed 300 kHz.

(c) The frequency stability of MICS transmitters shall be sufficient to maintain compliance with the emission limits of § 95.635 over the range:

(1) 12°C to 55°C in the case of medical implant transmitters; and

(2) 0°C to 70°C in the case of medical implant programmer/control transmitters.

10. Section 95.631 is amended by adding paragraph (h) to read as follows:

**§ 95.631 Emission types.**

\* \* \* \* \*

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

11. Section 95.633 is amended by adding paragraph (e) to read as follows:

**§ 95.633 Emission bandwidth.**

\* \* \* \* \*

(e) For transmitters in the MICS:

(1) The maximum authorized bandwidth is 300 kHz.

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

12. Section 95.635 is amended by revising paragraph (b) and adding paragraph (d) 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),<br>(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<br>before September 10, 1986 ..... | (2), (4), (7)                      |
| LPRS .....   | As specified in paragraph (c)   |                                    |
| MICS .....   | As specified in paragraph (d)   |                                    |
| <p>NOTE 1 - Filtering noted for GMRS and FRS transmitters refers to the requirement in § 95.637(b).</p> <p>NOTE 2 - Unwanted RF radiation may be stated in mean power or in peak envelope power, provided it is stated in the same parameter as TP.</p> <p>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.</p> <p>NOTE 4 - If spurious or harmonic emissions result in <i>harmful interference</i> (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.</p> |   |                                    |

(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,  $50 + 10 \log_{10} (TP)$  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  $43 + 10 \log_{10} (TP)$  dB on any frequency removed from the center of the authorized bandwidth by more than 250%.
- (8) At least  $53 + 10 \log_{10} (TP)$  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  $56 + 10 \log_{10} (TP)$  dB on any frequency removed from the center of the authorized bandwidth by more than 250%.

\* \* \* \* \*

(d) 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                        |
| Above 960       | 500                                       | 3                        |

NOTE - In the table above, the tighter limit applies at the band edges.

(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. The emission limit above 1 GHz is 5000  $\mu\text{V}/\text{m}$  as measured at 3 meters with 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 more than 150 kHz away from the center frequency shall be attenuated below the transmitter output power at least 20 dB, except as provided in § 95.635(d)(1).

13. Section 95.639 is amended by adding paragraph (f) to read as follows:

**§ 95.639 Maximum transmitter power.**

\* \* \* \* \*

(f) In the MICS the following limits apply:

(1) The maximum EIRP for programmer/control stations in the MICS is 25 microwatts, provided, however, that the antenna associated with the transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to the equipment authorization. The antenna and the transmitter shall be designed to ensure that no antenna other than that furnished by the holder of the equipment authorization for the transmitter shall be used with the transmitter.

(2) The maximum field strength from an inserted implant transmitter is 9.1  $\text{mV}/\text{m}$  (rms) at 3 meters as measured with an instrument having a peak detector function. The antenna for a medical implant transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to the equipment authorization for the transmitter.

(3) The average power radiated in any 300 kHz bandwidth shall not exceed 25 microwatts EIRP. See § 95.633(e)(4).

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

**§ 95.649 Power capability.**

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

15. 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, and a MICS transmitter.

16. 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, 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 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 1 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.

17. 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.

18. Subpart H is added to read as follows:

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

**§ 95.1101 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.

**§ 95.1103 Authorized locations.**

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

**§ 95.1105 Station Identification.**

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

**§ 95.1107 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.

**§ 95.1109 Permissible communications.**

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

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

(b) Except in response to a medical implant event, no medical implant transmitter shall transmit

except in response to a transmission from a medical implant programmer/control transmitter or a non-radio frequency actuation signal generated by a device external to the body in which the medical implant transmitter is implanted or is to be implanted.

**§ 95.1111 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.

(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.

**§ 95.1113 Antennas.**

No antenna for a MICS 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.

**§ 95.1115 Disclosure policies and registration.**

(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 any particular transmission from this transmitter will be free from interference."

(b) The holder of the grant of equipment authorization shall include with each MICS programmer/control transmitter a notice that the entity responsible for the operation of the MICS programmer/control transmitter shall, before using the device, register with the holder of the grant of equipment authorization. In the event that control of the device is transferred, it shall be reregistered in the name of the new entity having responsibility for its operation. The notice may be included with the instruction manual for the device or as a separate enclosure with the device. Such registration shall include the name and mailing address of the entity, the serial number of the programmer/control transmitter, and a telephone number for the entity that can be used to notify the entity if interference

from the programmer/control transmitter is suspected. Such registration information shall be maintained by the holder of the grant of equipment authorization for a period of at least ten years and made available, upon request, to the FCC in the event that interference from the device is suspected.

**§ 95.1117 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. Prior to initial operation, the entity that will be responsible for the operation of this device must register its name, mailing address, telephone number, and the serial number of this device with [name and address of equipment authorization grantee] as required by the FCC rules.

Note: In lieu of an address for the equipment authorization grantee, a telephone number may be provided. Where such devices are leased, the lessor may provide to the equipment authorization grantee the information required by this section with respect to each lessee.

(b) Where a medical implant programmer/controller 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.

**§ 95.1119 Marketing limitations.**

Transmitters intended for operation in the MICS may be marketed and sold only for those uses described in § 95.1109 of this chapter.