

(2) Mail: Comments by mail are to be addressed to the Bureau of Customs and Border Protection, Office of Regulations and Rulings, Border Security Regulations Branch, 1300 Pennsylvania Ave., NW. (Mint Annex), Washington, DC 20229.

(3) Hand delivery/courier: 799 9th Street, NW., Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Charles Perez, Program Manager, Office of Field Operations, Bureau of Customs and Border Protection (202-344-2605).

SUPPLEMENTARY INFORMATION:

Public Participation

The Bureau of Customs and Border Protection (CBP) invites interested persons to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the proposed rule. CBP also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rule. Comments that will provide the most assistance to CBP in developing these procedures will reference a specific portion of the proposed rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change.

Instructions: All submissions received must include the agency name and docket number for this rulemaking (USCBP-2005-0003). All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Submitted comments may also be inspected at the Bureau of Customs and Border Protection, 799 9th Street, NW., Washington, DC 20220. To inspect comments, please call (202) 572-8768 to arrange for an appointment.

Background

CBP published a document in the **Federal Register** (71 FR 40035) on July 14, 2006, proposing to amend the CBP Regulations pertaining to the electronic transmission of passenger manifests for commercial aircraft arriving in and departing from the United States and of passenger and crew manifests for commercial vessels departing from the United States. The proposed changes were designed to implement the mandate of the Intelligence Reform and Terrorism Prevention Act of 2004 to require screening of aircraft passengers and vessel passengers and crew traveling to and from the United States

against a government established terrorist watch list prior to departure. Thus, the proposed rule provides air carriers a choice to make manifest transmissions either for each passenger as passengers check in for the flight, up to but no later than 15 minutes prior to departure, referred to as APIS Quick Query (AQQ), or in batch form (a complete manifest containing data for all passengers) no later than 60 minutes prior to departure, referred to as APIS 60. The proposed rule also provides for vessel carriers transmitting passenger and crew manifests no later than 60 minutes prior to the vessel's departure from the United States. In addition, the proposed rule proposes to change the definition of "departure" for aircraft to mean the moment the aircraft pushes back from the gate to commence its approach to the point of takeoff (as opposed to the moment the wheels are drawn up into the aircraft just after takeoff).

The document invited the public to comment on the proposal, including the Regulatory Assessment containing an analysis of the expected economic impact of the changes. The Regulatory Assessment is posted on <http://www.regulations.gov> and on the CBP Web site at <http://www.cbp.gov> (it is also summarized in the proposed rule). Comments on the proposed rule were requested on or before August 14, 2006.

Extension of Comment Period

In response to the proposed rule published in the **Federal Register**, CBP has received comments from the Air Transport Association (ATA), the Air Carrier Association of America (ACAA), and the International Air Transport Association (IATA), requesting an extension of the comment period for an additional 60 days. CBP has determined to grant the requests for extension. Accordingly, the period of time for the submission of comments is being extended 60 days. Comments are now due on or before October 12, 2006.

Dated: July 28, 2006.

Deborah J. Spero,

Deputy Commissioner, Customs and Border Protection.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 95

[ET Docket No. 06-135; FCC 06-103]

Spectrum Requirements for Advanced Medical Technologies

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document focuses on ways to better accommodate the operation of implanted and body-worn medical transmitters in the 400 MHz band. These devices use wireless technologies for increasingly sophisticated and beneficial health care applications. Such applications currently include cardiac defibrillators for heart patients and real-time blood sugar monitoring devices for diabetics, and may, in the future, include applications as diverse as brain, muscle and nerve stimulation techniques for treating an array of conditions from Parkinson's disease to severe chronic depression. The Commission tentatively concludes that modifying its current rules and designating an additional two megahertz of spectrum in the adjacent 401-402 MHz and 405-406 MHz bands would appropriately provide needed capacity and more flexible operating rules for beneficial medical radio communication devices and thereby serve the public interest.

DATES: Comments must be filed on or before October 31, 2006, and reply comments must be filed on or before December 4, 2006.

FOR FURTHER INFORMATION CONTACT: Gary Thayer, Office of Engineering and Technology, (202) 418-2290, e-mail: Gary.Thayer@fcc.gov, TTY (202) 418-2989.

ADDRESSES: You may submit comments, identified by ET Docket No. 06-135 by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Federal Communications Commission's Web Site:* <http://www.fcc.gov/cgb/ecfs/>. Follow the instructions for submitting comments.

- *E-mail:* [Optional: Include the E-mail address only if you plan to accept comments from the general public].

Include the docket number(s) in the subject line of the message.

- *Mail:* [Optional: Include the mailing address for paper, disk or CD-ROM submissions needed/requested by your Bureau or Office. Do not include the Office of the Secretary's mailing address here.]

- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: FCC504@fcc.gov or phone: 202-418-0530 or TTY: 202-418-0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making and Notice of Inquiry*, ET Docket No. 06-135, FCC 06-103, adopted July 13, 2006, and released July 18, 2006. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY-A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room, CY-B402, Washington, DC 20554. The full text may also be downloaded at: <http://www.fcc.gov>.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: <http://www.fcc.gov/cgb/ecfs/> or the Federal eRulemaking Portal: <http://www.regulations.gov>. Filers should follow the instructions provided on the Web site for submitting comments.

- For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. 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, filers should send an e-mail to ecfs@fcc.gov, and include the following words in the body of the message, "get form." A sample form and directions will be sent in response.

- *Paper Filers:* 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 appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

- U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street, SW., Washington DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Summary of Notice of Proposed Rulemaking and Notice of Inquiry

1. The *Notice of Proposed Rule Making (NPRM) and Notice of Inquiry (Inquiry)*, focuses on ways to better accommodate the operation of implanted and body-worn medical transmitters in the 400 MHz band. These devices use wireless technologies for increasingly sophisticated and beneficial health care applications. Such applications currently include cardiac defibrillators for heart patients and real-time blood sugar monitoring devices for diabetics, and may, in the future, include applications as diverse as brain, muscle and nerve stimulation techniques for treating an array of conditions from paralysis to Parkinson's disease to severe chronic depression. The Commission tentatively concludes that modifying its current rules and

designating an additional two megahertz of spectrum would appropriately provide increased capacity and more flexible operating rules for beneficial medical radio communication devices and thereby serve the public interest.

2. Medtronic, Inc., filed a Petition for Rulemaking (Medtronic petition) proposing to establish a new service for implantable and body-worn medical radiocommunication devices in two megahertz of spectrum (at 401-402 MHz and 405-406 MHz) adjacent to the 402-405 MHz band currently authorized for the Medical Implant Communications Service (MICS). Medtronic states that this new allocation would complement the existing MICS allocation and support advances in medical sensor technology and the expected proliferation of such devices, especially those used for lower-cost medical monitoring and non-emergency reporting applications. Biotronik, Inc., has also filed a petition for rulemaking with proposals that conflict with those in the Medtronic petition, and that petition is also being considered.

3. As demonstrated by developments in the industry and by the response to the Medtronic petition for rulemaking, there is significant interest in using the 401-406 MHz MICS band for new diagnostic, therapeutic, and monitoring medical technologies. Based on the information provided by all parties, the FCC is proposing to add two additional megahertz of spectrum for implanted and body-worn medical transmitters to the existing MICS allocation at 402-405 MHz. It specifically proposes to add the 401-402 MHz and 405-406 MHz ("wing bands") to the existing MICS allocation. These bands appear well-suited for implanted and body-worn medical radio devices for the same reasons 402-405 MHz was originally designated for MICS, i.e., propagation characteristics, availability, and compatibility with other users. It asserts that the provision of contiguous spectrum will provide for the maximum efficiency of design and operation.

4. The FCC proposes to maintain the existing MICS rules in this spectrum, and continue to license use of MICS devices by rule. It further proposes to permit non-implanted antennas connected through the body to implanted devices under these rules. Accordingly, it will henceforth refer to this service as "Medical Device Radiocommunication Service," ("MedRadio"), to eliminate the implication that it is intended exclusively for implanted radios or implanted devices. It seeks comment on whether the various current MICS rules would continue to be appropriate for

operations under the new allocation, on the explicit inclusion of non-implanted transmitters, on whether or how to divide the spectrum between frequency agile and non-frequency-agile devices, and on whether certain medical devices as contemplated herein would be better served by a licensed operation regime.

5. In addition, the Commission seeks comment on whether there are some functions for which a narrower bandwidth is appropriate, and why, and whether there is sufficient justification for the more stringent attenuation limits described in the Medtronic petition. Commenters supporting emission limits other than those currently in the rules should provide technical analysis and practical rationale explaining why other limits would be more appropriate, and the relative difficulty or cost of compliance associated with their proposed limits. Commenters proposing a reduced field strength for body-worn transmitters should also provide technical analysis supporting their position.

6. The Commission also proposes to adopt rules for the 401–402 MHz and 405–406 MHz bands that would permit body-worn and implant transmitters having low-power and low duty cycles to operate without frequency monitoring capability, as suggested by Medtronic and supported by several commenters. Because such devices would pose a small risk of causing harmful interference, the Commission believes that permitting the operation of such devices without frequency monitoring could simplify devices, reduce their size, and extend their operational life. This could help lower the cost of medical data collection and therapy in both the care center and home environments, as well as provide physicians with an easy and accurate way to make routine adjustments to internal and external medical radio devices such as neural stimulators and insulin pumps. It suggests that providing additional spectrum for deployment of these devices could prove beneficial in keeping otherwise healthy individuals out of hospital beds and nursing facilities and allow many more individuals to live independently for a longer period of time. It seeks comment on the potential benefits of expanding the authority for operation of 400 MHz medical devices that do not employ frequency agility capabilities.

7. Specifically, it proposes to allow medical implant or body-worn devices and associated control station devices that operate without frequency agility at 401–402 MHz and 405–406 MHz to operate with an EIRP that does not exceed 250 nanowatts (nW) and a duty

cycle that does not exceed 0.1% during any one-hour interval. Based on the information available to us, this proposal appears to reflect a reasonable balance between the operational capabilities needed for devices to function properly and the need to minimize the risk of interference to other devices in the band. The Commission seeks comment on this proposal, including whether other power and duty cycle thresholds would be more appropriate, and what trade-offs they would entail.

8. It also notes Biotronik's contention that there is ample capacity in the current MICS allocation for a variety and large number of devices, and seeks additional comment on whether the additional spectrum proposed is needed for future medical devices, or whether such devices should be accommodated in the existing 402–405 MHz allocations, with appropriate modifications to the operational rules (100mw and 0.1%/day duty cycle), such as those proposed by Biotronik in its rulemaking petition. It also invites comment on whether the 401–406 MHz band should be apportioned differently among the various types of operation than as proposed, both in relative amounts of spectrum designated, and in the specific frequencies permitted for each type of operation. For instance, should a portion of spectrum be exclusively designated for non-frequency-monitoring devices, and if so, how much? Can the provision of exclusive spectrum for frequency monitoring devices be made unnecessary by appropriate restrictions on other devices? Is additional spectrum beyond that proposed above needed for implanted and body-worn medical radio devices? Comments suggesting the allocation of additional spectrum should discuss the basis for projecting future types of uses and needs.

9. While the present MICS rules can be read to have assumed that an implant transmitter, as part of an implant device, would be located under the skin, it is now apparent that transmitters for implanted devices can, in many cases, be located on the surface of the skin. Additionally, it appears that there are body-worn devices that can perform critical diagnostic, therapeutic, and monitoring functions, and the Commission proposes to accommodate such devices in our rules. In both cases, the Commission believes that it is the location of the transmitter, not the medical device, that should dictate its operational parameters, as it is the location that will determine its communication capability and its interference potential. It proposes to

modify the rules to so provide. It also seeks comment on Medtronic's proposed definition of a body-worn transmitter as one "intended to be placed on or in very close proximity (six centimeters or less) to the human body used to facilitate communications from a medical body-worn or implanted device."

10. The Commission proposes to focus on providing flexibility in the use of spectrum for implanted and body-worn medical radio devices. The Commission notes that the Medtronic petition suggests distinctions depending upon factors such as whether a device uses spectrum intensively or is used for life-critical applications. The Commission asserts that it is neither its role, nor its area of expertise, to adopt rules that would define operating criteria based upon such determinations. Instead, medical device manufacturers should be cognizant of the potential health and safety risks that could arise if implanted or body-worn medical radiocommunication devices are subjected to various levels of RF interference in a dynamic and unpredictable RF environment, and design their products with appropriate safeguards and robustness as is appropriate to their function. It further suggest that such concerns are more appropriately taken into consideration and evaluated as part of the FDA medical device approval process. Therefore, the it declines to propose any rules based upon such criteria, and seeks comment on this position.

11. Part 15 of the FCC's rules restricts radiation from unlicensed devices in certain frequency bands ("restricted bands") to spurious emissions only. The 90–110 kHz band is included among the restricted bands in order to protect incumbent the Loran-C operations.

12. Guidant Corporation (Guidant) (now Boston Scientific) states that it is unclear how induction devices fit under the Commission's restricted band prohibition of § 15.205, and asks the Commission to amend the part 95 rules to include medical implant devices such as those made by Guidant that use inductive telemetry in the 90–110 kHz band. More specifically, it requests that the Commission provide a narrow exception to the part 15 restricted band prohibitions for medical implants or, preferably, amend the MICS rules to expressly include all implants, including those that operate inductively in the 90–110 kHz band.

13. The FCC seeks comment on whether inductive devices such as those made by Guidant should be authorized to operate if they produce RF energy in the 90–110 kHz band. It asks

commenters to address the advantages and disadvantages of allowing or prohibiting such operation, including the resulting interference potential. If such operation were to be permitted, what approach should be taken? For example, similar to the modified MedRadio rules proposed herein, a secondary allocation for inductively coupled medical devices could be created in the 90–110 kHz band on a licensed-by-rule basis under part 95. Another option would be to provide an exception to the restricted band spurious emission limits for unlicensed medical devices that use inductive coupling in the 90–110 kHz band. Alternatively, a waiver could be granted that would permit manufacture, sale, and use of such devices for a limited period of time until devices fully compliant with the present rules can be developed. It invites commenters to address the relative merits of these options, and to suggest any other options. It also seeks comment on the more general question raised by Guidant concerning how to address emissions from medical implant devices that employ inductive coupling technology for communicating with associated external devices.

14. The Commission also begins an Inquiry into additional developments that are anticipated in the medical devices field and their likely spectrum requirements that will enable us to subsequently develop proposals for additional rules as may be appropriate for their operation, based on the input received. Increasing numbers of implanted and body-worn medical devices will rely upon wireless radiocommunication technologies for increasingly sophisticated therapies. These include devices to assist in everything from motor function to eyesight, significantly mitigating the effects of once debilitating injuries or diseases. Accordingly, we seek to develop a comprehensive record concerning the present and future RF spectrum requirements as well as device immunity issues with respect to these medical radio devices in order to better inform our current rulemaking effort and to provide a basis for further rule changes. The Commission seeks information concerning new and anticipated implant and body-worn medical radiocommunication technologies and how it can anticipate and proactively address the challenging array of RF spectrum sharing issues raised by their increasing use, including the protection of user health and safety when implants receive interference from primary allocated services in the band.

The Commission seeks comment on the relative benefits and tradeoffs that should be considered with respect to both licensed and unlicensed approaches to authorizing the operation of these devices.

15. Finally, the Commission also seeks comment on collaborative efforts between the Commission (FCC) and the U.S. Food and Drug Administration (FDA) regarding options for better educating device manufacturing industry leaders and RF wireless technology leaders about medical radio device electromagnetic compatibility (EMC) coexistence issues in an RF environment. The Commission's goal is to create an environment that fosters continuing advances in medical devices through flexible RF spectrum allocations with the minimum FCC regulatory requirements that are necessary for efficient use of the spectrum and to ensure patient safety.

Initial Regulatory Flexibility Analysis

16. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),¹ the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the *Notice of Proposed Rule Making* (NPRM). 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 provided in paragraph 53 of the NPRM. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).²

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

17. In this proceeding, the Commission explores future spectrum requirements for advanced medical devices that use wireless radiocommunication technologies. Wireless technologies are increasingly being used in medical devices for a variety of purposes ranging from basic telemetry transmission to more sophisticated health care applications.³ Our focus in this proceeding is primarily on implanted and body-worn

¹ See 5 U.S.C. 603. The RFA, see 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Public Law 104–121, Title II, 110 Stat. 847 (1996).

² See 5 U.S.C. 603(a).

³ Telemetry is the use of telecommunication for automatically indicating or recording measurements at a distance from the measuring instrument. 47 CFR 2.1.

medical radiocommunication devices (MRDs) that serve to actively manage and maintain body function/health conditions.⁴ Technological advances in this field are evolutionizing health care for the benefit of all Americans. Our goal is to create an environment that fosters continuing advances through flexible RF spectrum allocations and reduced regulatory requirements.

18. Based on the responses we have received to a Petition for Rulemaking from Medtronic, Inc., the Commission believes that there is need for additional spectrum in the 400 MHz range for implanted and body-worn MRDs. Thus, in the Rulemaking portion of this proceeding, the Commission proposes to allocate two megahertz of spectrum for use by MRDs in the 401–402 MHz and 405–406 MHz bands that are adjacent to the existing Medical Implant Communication Service (MICS) allocation in the 402–505 MHz band. The Commission seeks comment on establishing a new Medical Data Service (MEDS) that would encompass all MRDs operating in the entire 401–406 MHz band.

B. Legal Basis

19. The proposed action is authorized under sections 1, 4(i), 7(a), 301, 303(f), 303(g), 303(r), 307, 316, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. sections 151, 154(i), 157(a), 301, 303(f), 303(g), 303(r), 307, 316, and 332.

C. Description and Estimate of the Number of Small Entities To Which the Proposed Rules Will Apply

20. 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.⁵ The RFA generally defines the term “small entity” as having the same meaning as the terms “small business,” “small organization,” and “small governmental jurisdiction.”⁶ In addition, the term “small business” has the same meaning as the term “small business concern”

⁴ Part 95 of the Commission's rules define “medical implant transmitter” as a “* * * transmitter that operates or is designed to operate within the human body for the purpose of facilitating communications from a medical implant device.” See *Appendix 1 to Subpart E of Part 95—Glossary of Terms* (following 47 CFR 95.673). The term “body-worn” is not defined by our current rules, however, as discussed in Rulemaking herein, we propose to adopt an analogous definition for medical body-worn transmitters namely, a “transmitter intended to be placed on or in very close proximity (*i.e.*, 6 centimeters or less) to the human body used to facilitate communications from a medical body-worn or implanted device.”

⁵ 5 U.S.C. 603(b)(3).

⁶ 5 U.S.C. 601(6).

under the Small Business Act.⁷ A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.⁸

21. Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.⁹ A "small organization" is generally "any not-for-profit enterprise which is independently owned and operated and is not dominant in its field."¹⁰ Nationwide, as of 2002, there were approximately 1.6 million small organizations.¹¹ The term "small governmental jurisdiction" is defined generally as "governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand."¹² Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.¹³ We estimate that, of this total, 84,377 entities were "small governmental jurisdictions."¹⁴ Thus, we estimate that most governmental jurisdictions are small.

Personal Radio Services. We are proposing to place the MEDS within part 95 of our rules ("Personal Radio Services"). Personal radio services provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under part 95 of our rules.¹⁵ Many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the mostly unlicensed and shared nature of the spectrum utilized in many

of these services, the Commission lacks direct information other than the census data above, upon which to base an estimation of the number of small entities under an SBA definition that might be directly affected by the proposed rules.

Wireless Service Providers. The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of "Paging"¹⁶ and "Cellular and Other Wireless Telecommunications."¹⁷ Under both categories, the SBA deems a wireless business to be small if it has 1,500 or fewer employees. For the census category of Paging, Census Bureau data for 2002 show that there were 807 firms in this category that operated for the entire year.¹⁸ Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.¹⁹ Thus, under this category and associated small business size standard, the majority of firms can be considered small. For the census category of Cellular and Other Wireless Telecommunications, Census Bureau data for 2002 show that there were 1,397 firms in this category that operated for the entire year.²⁰ Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.²¹ Thus, under this second category and size standard, the majority of firms can, again, be considered small.

Public Safety Radio Services. Public Safety radio services include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services.²² For

small businesses in this category, the above small business size standard applies to 1500 or fewer employees. There are a total of approximately 127,540 licensees in these services. Governmental entities²³ as well as private businesses comprise the licensees for these services. All governmental entities with populations of less than 50,000 fall within the definition of a small entity.²⁴

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

22. We propose a licensing approach for the 401–402 MHz and 405–406 MHz wing bands identical to that used for the existing MICS center band. Thus, rather than require individual transmitter licensing, we propose to authorize operation by rule within the Citizens Band (CB) Radio Service under part 95 of our rules and pursuant to section 307(e) of the Communications Act.²⁵ Under this proposal, licensing would be accomplished through adherence to applicable technical standards and other operating rules (unlicensed operations). We tentatively conclude that this approach is beneficial because it would minimize the administrative burden on prospective licensees as compared with an individual licensing. We seek comment on this proposal. Commenters

companies as well as units under governmental control. The local government service that is presently comprised of approximately 41,000 licensees that are state, county, or municipal entities that use the radio for official purposes not covered by other public safety services. There are approximately 7,000 licensees within the forestry service which is comprised of licensees from state departments of conservation and private forest organizations who set up communications networks among fire lookout towers and ground crews. The approximately 9,000 state and local governments are licensed to highway maintenance service provide emergency and routine communications to aid other public safety services to keep main roads safe for vehicular traffic. The approximately 1,000 licensees in the Emergency Medical Radio Service (EMRS) use the 39 channels allocated to this service for emergency medical service communications related to the delivery of emergency medical treatment. 47 CFR 90.15–90.27. The approximately 20,000 licensees in the special emergency service include medical services, rescue organizations, veterinarians, handicapped persons, disaster relief organizations, school buses, beach patrols, establishments in isolated areas, communications standby facilities, and emergency repair of public communications facilities. 47 CFR 90.33–90.55.

²³ 47 CFR 1.1162.

²⁴ 5 U.S.C. 601(5).

²⁵ See Medtronic Petition at i, 16, and Appendix A, at proposed section 95.1601. We note that 47 U.S.C. 307(e)(3) provides that the term "citizens band radio service" shall have the meaning given it by the Commission by rule. 47 U.S.C. 307(e)(1) provides that upon determination by the Commission that an authorization serves the public interest, convenience, and necessity, the Commission may by rule authorize the operation of radio stations without individual licenses in the citizens band radio service.

⁷ 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).

⁸ Small Business Act, 15 U.S.C. 632 (1996).

⁹ See SBA, Programs and Services, SBA Pamphlet No. CO-0028, at page 40 (July 2002).

¹⁰ 5 U.S.C. 601(4).

¹¹ Independent Sector, The New Nonprofit Almanac & Desk Reference (2002).

¹² 5 U.S.C. 601(5).

¹³ U.S. Census Bureau, Statistical Abstract of the United States: 2006, Section 8, page 272, Table 415.

¹⁴ We assume that the villages, school districts, and special districts are small, and total 48,558. See U.S. Census Bureau, Statistical Abstract of the United States: 2006, section 8, page 273, Table 417. For 2002, Census Bureau data indicate that the total number of county, municipal, and township governments nationwide was 38,967, of which 35,819 were small. *Id.*

¹⁵ 47 CFR part 90.

¹⁶ 13 CFR 121.201, NAICS code 517211.

¹⁷ 13 CFR 121.201, NAICS code 517212.

¹⁸ U.S. Census Bureau, 2002 Economic Census, Subject Series: "Information," Table 5, Employment Size of Firms for the United States: 2002, NAICS code 517211 (issued Nov. 2005).

¹⁹ *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with "1000 employees or more."

²⁰ U.S. Census Bureau, 2002 Economic Census, Subject Series: "Information," Table 5, Employment Size of Firms for the United States: 2002, NAICS code 517212 (issued Nov. 2005).

²¹ *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with "1000 employees or more."

²² With the exception of the special emergency service, these services are governed by Subpart B of part 90 of the Commission's Rules, 47 CFR 90.15–90.27. The police service includes approximately 27,000 licensees that serve state, county, and municipal enforcement through telephony (voice), telegraphy (code) and teletype and facsimile (printed material). The fire radio service includes approximately 23,000 licensees comprised of private volunteer or professional fire

are invited to address whether other licensing approaches should be considered and discuss the relative benefits and disadvantages compared to our proposal.

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

23. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.²⁶

24. We propose to establish a new Medical Data Service (MEDS) under Part 95 that would encompass all medical devices permitted to operate in the entire 401–406 MHz band. We seek comment on options concerning whether and how the five megahertz of spectrum that would comprise this proposed MEDS band could be divided among the evolving varieties of implanted and body-worn medical transmitters, including low-power, low-duty-cycle (LPLDC) devices without listen-before-talk (LBT).

25. For example, should both implantable and body-worn transmitters be permitted to operate in all, or just selected portions, of the five megahertz of the proposed 401–406 MHz MEDS band? Should the same technical standards that govern the existing MICS center band transmitters be applied uniformly across the entire band? Should an adjustment in the permissible operating power of body-worn transmitters be made to account for difference in body tissue attenuation as compared with implantable devices? Similarly, should LPLDC devices without LBT be permitted to operate throughout the entire five megahertz of the proposed MEDS band or be limited to segments such as the 401–402 MHz and 405–406 MHz wing bands? Why or why not? Commenters should explain the rationale, and corresponding benefits and disadvantages, for whatever approach is recommended. Are there any other factors that should be considered with respect to distinguishing the applicable rules for

implantable, body-worn devices, and LPLDC transmitters? Should other types of medical radiocommunication devices be considered for operation in this proposed MEDS band? We especially seek small entity comment on these issues.

E. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

26. None.

Initial Paperwork Reduction Analysis

27. The *Notice of Proposed Rule Making* contains proposed new or modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due 60 days after the date of publication in the **Federal Register**. Comments should address: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, we seek specific comment on how we might “further reduce the information collection burden for small business concerns with fewer than 25 employees.”

Ordering Clauses

28. Pursuant to sections 1, 4(i), 7(a), 301, 303(f), 303(g), 303(r), 307, 316, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. sections 151, 154(i), 157(a), 301, 303(f), 303(g), 303(r), 307, 316, and 332, the *Notice of Proposed Rule Making and Notice of Inquiry, is adopted*.

29. The Biotronik *Request for Extension of Waiver*, is granted until one year from the effective date of final rules adopted in this proceeding.

30. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of the *Notice of Proposed Rule Making and Notice of Inquiry*, including the Initial

Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in Parts 2 and 95

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E6–12500 Filed 8–1–06; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 25

[IB Docket No. 06–123; FCC 06–90]

Establishment of Policies and Service Rules for the Broadcasting-Satellite Service

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Communications Commission proposes application processing and service rules for the 17/24 GHz Broadcasting Satellite Service (BSS). The Commission proposes and/or seeks comment on a number of issues, including: licensing procedures, posting of performance bonds, milestone schedules, limits on pending applications, annual reporting, license terms, replacement satellites, access to the U.S. market from non-U.S. satellites; public interest obligations, copyright and broadcast carriage, equal employment opportunity, geographic service coverage, and emergency alert system participation; use of internationally allocated spectrum by receiving stations located outside the United States; orbital spacing and antenna performance standards; technical requirements for intra-service sharing; other technical requirements, such as reverse band operations, tracking, telemetry, and command operations, polarization, and full frequency re-use requirements; and technical requirements for inter-service sharing in the 17 and 24 GHz bands.

DATES: Comments are due on or before October 16, 2006 and reply comments are due on or before November 15, 2006. Public and agency comments on the Initial Paperwork Reduction Act of 1995 (IFRA) analysis are due October 2, 2006.

ADDRESSES: You may submit comments, identified by IB Docket No. 06–123, by any of the following methods:

²⁶ See 5 U.S.C. 603(c).