environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This final action is not subject to *Executive Order* 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under *Executive Order* 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final action does not involve technical standards; therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898—Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. Therefore, Executive Order 12898 does not apply to this final action.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This final action is not a ''major rule'' as defined by 5 U.S.C. 804(2). Therefore, this final action will be effective on May 14, 2009.

L. Judicial Review

Under CAA section 307(b), judicial review of this final action is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit on or before July 13, 2009. Under CAA section 307(d)(7)(B), only those objections to the final rule that were raised with specificity during the period of public comment may be raised during judicial review. Moreover, under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by EPA to enforce these requirements.

VI. Statutory Authority

The statutory authority for this action is provided by sections 307(d)(7)(B), 101, 111, 114, 116, and 301 of the CAA as amended (42 U.S.C. 7401, 7411, 7414, 7416, and 7601). This notice is also subject to section 307(d) of the CAA (42 U.S.C. 7407(d)).

List of Subjects

40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Baseline emissions, Intergovernmental relations, Aggregation, Major modifications, Reporting and recordkeeping requirements.

40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Baseline emissions, Incorporation by reference, Intergovernmental relations, Aggregation, Major modifications, Reporting and recordkeeping requirements.

Dated: May 8, 2009.

Lisa P. Jackson,

Administrator.

[FR Doc. E9–11271 Filed 5–13–09; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 2 and 95

[ET Docket Nos. 06–135, 05–213 and 03–92, RM–11271; FCC 09–23]

Spectrum Requirements for Advanced Medical Technologies

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document establishes a new Medical Device Radiocommunication Service (MedRadio Service) of the Commission's rules. This new service incorporates the existing Medical Implant Communications Service (MICS) ''core'' band at 402–405 MHz, and also includes two megahertz of newly designated spectrum in the adjacent ''wing'' bands at 401–402 MHz and 405–406 MHz. The MedRadio Service will accommodate the operation of body-worn as well as implanted medical devices, including those using either listen-before-talk (''LBT'') frequency monitoring or non-LBT spectrum access methods, in designated portions of the 401–406 MHz band.

DATES: Effective August 12, 2009.

FOR FURTHER INFORMATION CONTACT: Gary Thayer, (202) 418–2290, e-mail *Gary.Thayer@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* ET Docket Nos. 06–135, 05–213, and 03–92, RM–11271, FCC 09–23, adopted March 19, 2009, and released March 20, 2009. The full text of this document is available on the Commission's Internet site at *http://www.fcc.gov.* It is also available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th St., SW., Washington, DC 20554. The full text of this document also may be purchased from the Commission's duplication contractor, Best Copy and Printing Inc., Portals II, 445 12th St., SW., Room CY–B402, Washington, DC 20554; telephone (202) 488–5300; fax (202) 488–5563; e-mail *FCC@BCPIWEB.COM.*

Summary of the Report and Order

1. *Overview.* In July 2006, the Commission adopted a Notice of Proposed Rulemaking (NPRM), Notice of Inquiry (NOI) and Order—collectively, the *MedRadio NPRM.* In the *MedRadio NPRM,* the Commission proposed to establish a new service for medical radiocommunication devices to better accommodate the varieties of new implantable and body-worn medical devices.

2. In this Report and Order, the Commission decided to establish a new Medical Device Radio-communication Service (MedRadio Service) under part 95 of the Commission's rules. Under the rules adopted by the Commission in this Report and Order, this new service incorporates the existing Medical Implant Communications Service (MICS) ''core'' band at 402–405 MHz, and also includes two megahertz of newly designated spectrum in the adjacent ''wing'' bands at 401–402 MHz and 405–406 MHz. Thus, the MedRadio Service will provide a total of five megahertz of contiguous spectrum on a secondary basis and non-interference basis for advanced wireless medical radiocommunication devices used for diagnostic and therapeutic purposes in humans. In addition, the MedRadio Service will accommodate the operation of body-worn as well as implanted medical devices, including those using either listen-before-talk (''LBT'') frequency monitoring or non-LBT spectrum access methods, in designated portions of the 401–406 MHz band.

3. The Commission found that the new MedRadio spectrum in the 401–402 MHz and 405–406 MHz wing bands is well suited for use on a secondary basis by the medical implant and body-worn devices covered by this Order for several reasons. First, these frequencies offer the same propagation, availability, and compatibility characteristics that were found to be favorable for the MICS in the 402–405 MHz core band. In addition, this new designation will result in a continuous span of spectrum (from 401–406 MHz) that matches the five-megahertz of spectrum that is also designated internationally for similar use by medical implant and body-worn devices.

4. The Commission noted that the service and technical rules adopted in this Report and Order for the MedRadio Service are based upon the existing MICS rules, and include modified spectrum sharing requirements in the new wing bands. The new rules will permit the use of both medical implant devices and medical body-worn devices in specified segments of the 401–406 MHz band.

5. The Commission found that these new MedRadio sharing rules will provide a greater degree of flexibility than is permitted by the existing medical implant rules, while also assuring spectrum use compatibility among different device types. The Commission further found that the new designation in the wing bands will provide the additional shared spectrum that is urgently needed for operation of both implant and body-worn devices. The Commission stated its further belief that the MedRadio rules adopted in this Order should encourage the continuing use of the legacy MICS core band predominantly for life-critical applications, such as those served by the existing population of medical implant devices presently used.

6. With respect to the potential for interference to incumbent users of the 401–402 MHz and 405–406 MHz wing bands arising from the operation of MedRadio devices, the Commission concluded that the potential for such interference is negligibly small. The Commission noted that, in the United States, the 401–406 MHz band is allocated for various Federal and non-Federal uses on a primary basis, and the 402–405 MHz band is allocated for mobile, except mobile aeronautical, service on a secondary basis, with use limited to MICS. The Commission determined that, given the ultra low power limits and intermittent operating modes that will be used by these medical devices, and the expectation of large separation distances, there is little likelihood that these medical devices could cause harmful interference to incumbent operations.

7. With respect to the potential for harmful effects to MedRadio devices due to received interference from incumbent users, the Commission observed that it would be beneficial if MedRadio devices employed robust designs. For example, the Commission noted that MedRadio medical devices—particularly those devices used for life critical and time-sensitive applications—might need to employ a variety of error detection and correction techniques, frequency monitoring capabilities, and re-transmission protocols.

8. In broader terms, the Commission determined that the additional spectrum and enhanced flexibility afforded in the new rules will promote the accelerated development of newer generations of advanced medical device technologies. These advances, the Commission found, will herald dramatic improvements in therapeutic/diagnostic patient care and quality of life for countless individuals. The Commission also noted that the MedRadio designation and rules adopted in this Order are harmonized for the most part in their general approach with similar European Telecommunication Standards Institute (ETSI) standards relating to use of the 401–406 MHz band by medical implant and body-worn devices in other regions of the world. The Commission stated its belief that such harmonization will serve the public interest by offering Americans greater confidence of reliable device operation while traveling abroad, and conversely, by offering similar confidence for foreign visitors to the United States. The Commission also determined that economies of scale resulting from harmonized rules for domestic manufacturers seeking to compete in the world market should foster a reduction of device prices, thus making the benefits of such technologies more widely available and affordable for the American public.

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

10. *Definitions—Implant and Body-worn Devices.* In order to be deemed a *medical body-worn device* or *medical body-worn transmitter,* the Commission required that the antenna of the associated patient-worn device be placed upon or in very close proximity (*e.g.,* within a few centimeters) to the body. In order to be classified as a *medical implant transmitter* or *medical implant device,* the Commission required that the transmitting antenna of the patient device must itself be implanted wholly within the body—which would include any point below the skin, or more deeply within the body. The Commission retained the

existing definitions for medical implant devices.

11. *Authorized Frequencies for Implant and Body-Worn Devices.* The Commission concluded that implanted devices will be permitted in both the existing MICS core band at 402–405 MHz, as well as in the wing bands at 401–402 MHz and 405–406 MHz. This will allow medical implant devices to operate anywhere in the 401–406 MHz band—but subject to different technical requirements in the core and wing bands.

12. The Commission decided, with one exception, to permit body-worn devices to operate only in the wing bands at 401–402 MHz and 405–406 MHz. Thus, in the new MedRadio wing bands, both implant and body-worn devices will be allowed to operate—under common technical requirements for each—throughout both the 401–402 MHz and 405–406 MHz frequency range. The Commission stated its belief this approach will serve to accommodate a greater variety of implant and body-worn devices. The Commission also observed that, by preserving the core band at 402–405 MHz primarily for communications involving deeply implanted devices, these frequencies would likely continue to be used largely for life-critical medical devices such as cardiac defibrillators.

13. As an exception to the general rule for body-worn devices, the Commission decided to permit the operation in the core band of temporary body-worn devices that are used to evaluate the efficacy of an implanted medical device.

14. The Commission determined that allowing the operation of such temporary body-worn devices will enhance the therapeutic and diagnostic options available to patients. In particular, the Commission noted that this will allow physicians to better evaluate the efficacy of proposed treatments involving implanted devices prior to actual device implantation. The Commission decided to permit the operation of such temporary body-worn devices on any frequency in the 402–405 MHz core band provided that: (1) Such external operation is limited solely to evaluating with a patient the efficacy of a fully implanted permanent medical device that is intended to replace the temporary body-worn device; (2) RF transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary due to unforeseen circumstances; (3) the maximum output power of the external, temporary body-worn device shall not exceed 200 nW EIRP; and (4) the external device must comply fully with all other MedRadio rules described throughout the core 402–405 MHz band.

15. The Commission declined to explicitly limit the core band to life-critical and time-sensitive applications, or to designate the wing bands for non-life-critical, non-time sensitive applications. The Commission said that its decision to limit the core band primarily to communications involving implanted devices, coupled with the technical rules adopted for use of the core and wing bands will achieve much the same result, while providing greater flexibility for device manufacturers and practitioners. The Commission determined that leaving the ultimate decision on these matters to health care professionals and medical device manufactures, in concert with FDA-required risk management processes, would result in better and more flexible use of this scarce spectrum resource.

16. *Permissible Communications and Operator Eligibility.* The Commission concluded that the new MedRadio service will be governed by the same operator eligibility and permissible communications requirements that pertain to the legacy MICS. According to the Commission, this will result in a more beneficial use of the spectrum than alternative approaches.

17. More specifically, the Commission decided that MedRadio devices may be used only by persons for diagnostic and therapeutic purposes, and only when provided for such purposes to a human patient under the direction of a duly authorized health care professional. Furthermore, the Commission limited the MedRadio service to the transmission of non-voice data. MedRadio programmer/control transmitters may not relay information on MedRadio frequencies to a receiver that is not included with a MedRadio device. The Commission concluded that these requirements are central to maintaining the originally intended character and utility of this spectrum, which the Commission found has proven to be of significant benefit to many patients over the years.

18. The Commission declined to adopt rules in this Order that would permit the operation of wireless hearing aids in the upper portion of the lower MedRadio wing band. However, in recognition of the important public interest benefits associated with this proposal, the Commission welcomed additional technical submissions or revisions to address whether this or some other band(s) could accommodate various types of hearing aid devices, and stated that it would consider developing a record through a notice of proposed rulemaking to more fully analyze these matters.

19. The Commission also declined to allow the use of MedRadio devices in connection with animal test subjects in the course of human drug research. The Commission found that such testing would not, in and of itself, directly perform any diagnostic or therapeutic function for a human patient. In contrast, the Commission observed that, since its creation, the legacy MICS had been explicitly reserved for use by devices performing diagnostic and therapeutic functions with *human* patients and only when such use has been duly authorized by a health care professional. It further found that changing the eligibility requirements to permit animal test subject use would constitute a major departure from these underlying requirements and that such a departure did not appear to be warranted based upon the record in this proceeding. From a procedural perspective, the Commission further stated that the *MedRadio NPRM* neither proposed, nor sought comment on, modifying these basic service and eligibility provisions; and that it particularly did not address the specific question at issue here of whether use of the MICS/MedRadio frequencies should be extended to animal testing. Thus, the Commission concluded that it had an insufficient substantive record or procedural notice upon which to pursue the matter of animal test subjects.

20. *MedRadio channels.* The Commission decided to generally carry forward the MICS rules into the new MedRadio Service. Under the existing rules, no particular channeling scheme is specified for the operation of MICS devices. Instead, a ''channel'' is simply defined as any continuous segment of spectrum used by a medical device. Thus, a MedRadio device may transmit on any center frequency so long as the maximum authorized emission bandwidth is not exceeded. The Commission stated its belief that this approach is beneficial because it would continue to provide the greater flexibility that device manufacturers now use as compared with a rigid channeling scheme.

21. *Emission Bandwidth.* With respect to the new MedRadio wing bands at 401–402 MHz and 405–406 MHz, the Commission concluded that a 100 kilohertz maximum authorized emission bandwidth in the limited space of the one-megahertz wide wing bands will foster more intensive spectrum utilization by a greater number of devices as compared with a 300

kilohertz maximum bandwidth. The Commission determined that this smaller bandwidth would allow more devices to use the wing bands on non-overlapping spectrum. In addition, the Commission found that this bandwidth will also serve to minimize interference potential from other MedRadio devices, particularly in light of the fact that both LBT and non-LBT devices will share the entire wing bands.

22. As one exception to the general bandwidth requirement for the wing bands, the Commission decided to allow up to a 150 kilohertz maximum authorized emission bandwidth at 401.85–402 MHz. In reaching this decision, the Commission recognized that some body worn devices, such as the glucose monitoring devices that are now operating in the core band under a waiver, need a slightly wider emission bandwidth. Thus, the Commission found that its decision here to allow a slightly wider emission bandwidth at the upper edge of the 401–402 MHz wing band will facilitate transitioning such devices now operating under rule waivers out of the core band. In addition, the Commission observed that the narrower bandwidth for the wing bands, is expected to be better suited for non-life-critical devices—namely, those with less severe battery life constraints that are tailored for operation with lower bandwidth data streams utilizing a relatively greater number of longer data transmission sessions as compared with devices used in the core band.

23. For the core band at 402–405 MHz, the Commission decided to maintain the existing maximum authorized emission bandwidth of 300 kilohertz. The Commission found that, relative to the 100 kilohertz bandwidth it adopted for the wing bands, this 300 kilohertz bandwidth will better facilitate more data-intensive transmissions of shorter duration which tend to be more energy efficient, and thus prolong battery life for implants. This will also support higher data transmission rates than could be accommodated by the maximum authorized emission bandwidth of 100 kilohertz channels of the wing bands, and thus may be more desirable for certain applications. The Commission found that such characteristics are especially beneficial in extending the battery life of deep implant devices.

24. The Commission decided that it would continue to permit MedRadio transmitters to utilize full duplex or half duplex communications if the total amount of bandwidth used by all of the MedRadio channels employed by a MedRadio device during a MedRadio communications session does not exceed the maximum authorized emission bandwidth (*i.e.,* 100 kilohertz in the wing bands and 300 kilohertz in the core band). Moreover, smaller bandwidths may be employed by a single MedRadio device so long as the device adheres to all other EIRP and unwanted emission limits. For example, a single MedRadio device operating in the wing bands could be designed to operate nominally on two channels, each having a maximum emission bandwidth of 50 kilohertz, because the communications session would, in aggregate, be 100 kilohertz. The Commission noted that, in essence, these provisions carry forward the existing channel use provisions of the MICS rules into the new MedRadio rules.

25. *Frequency monitoring requirement.* In the Report and Order, the Commission observed the current MICS rules require that the programmer/control transmitter associated with a medical implant device in the 402–405 MHz band must incorporate a frequency monitoring mechanism to monitor the channel or channels that the medical device transmitters intend to occupy. The Commission further stated its belief that an LBT frequency monitoring requirement is beneficial because it facilitates spectrum sharing among many uncoordinated devices and can reduce the likelihood of harmful interference from federal systems that are allocated on a primary basis. Thus, the Commission decided to maintain the current frequency monitoring protocol specified in the form MICS rules as a general requirement for implant devices permitted throughout the entire 401–406 MHz MedRadio core band, as well as for body-worn devices permitted in the new wing bands. In addition, the Commission also extended the ''medical implant event'' exception of the current rules to LBT-enabled implant devices operating throughout the 401–406 MHz MedRadio band.

26. In further recognition of the potential advantages of non-LBT spectrum access methods for certain low power, low duty cycle (LP–LDC) devices—particularly, in terms of extended battery life, reduced complexity, and lower device cost to patients—the Commission decided to permit the use of non-LBT spectrum access methods in the wing bands, with certain transmitter power and duty cycle limits, by both implant and body-worn devices. In addition, the Commission permitted the use of non-LBT spectrum access methods for implant devices that operate with an emission bandwidth not exceeding 300 kilohertz centered at 403.65 MHz in the existing core band with certain transmitter power and duty cycle limits. Finally, the Commission also decided to permit the operation on any of the frequencies in the 402–405 MHz band of temporary body-worn transmitting devices that are used solely during a limited patient evaluation period in order to determine the suitability of a fully implanted device, provided that they fully comply with all other MedRadio rules applicable to the band.

27. *Transmitter power and duty cycle.* The Commission limited the maximum EIRP of LBT-enabled implant devices throughout the 401–406 MHz band and LBT-enabled body-worn medical devices in the wing bands to 25 microwatts EIRP. The Commission determined that, as with the original MICS rules, this limit is intended to ensure efficient spectrum sharing and compatibility among multiple uncoordinated devices. Furthermore, the 25 microwatt limit will maintain continuity with the present EIRP limit and LBT frequency monitoring requirement for the core band (which we also maintain under the new MedRadio rules) that has served well for spectrum access.

28. With respect to access to the 402–405 MHz band by non-LBT devices, the Commission found that the convergence of comments in the record, particularly subsequent to the adoption by ETSI of similar standards, supported permitting operation by such devices with a total emission bandwidth not exceeding 300 kilohertz, centered at 403.65 MHz, with a maximum EIRP of 100 nanowatts and with maximum duty-cycle and transmission session limits of 0.01% and ten per hour, respectively. The Commission stated that its decision was informed by the increasingly widespread adoption of standards internationally that provide for non-LBT spectrum access methods in the 402–405 MHz band. Furthermore, based upon the Commission's prior experience with single-channel non-LBT devices operating under rule waivers in the core MICS band the Commission concluded that these EIRP and duty cycle limits would be sufficiently conservative to permit efficient spectrum sharing between LBT enabled and non-LBT devices that choose to operate at 403.65 MHz.

29. For devices using non-LBT spectrum access methods in the new MedRadio wing bands at 401–402 and 405–406 MHz, the Commission adopted power and duty cycle limits that match the proposals in the *MedRadio NPRM,* namely a maximum EIRP of 250 nanowatts, together with a maximum

duty cycle limit of 0.1% and a maximum limit of 100 communication sessions per hour. The Commission stated its belief that permitting the higher EIRP of 250 nanowatts for non-LBT operation in the wing bands, as compared with the 100 nanowatts adopted for non-LBT operation in the core band, will serve to encourage use of the wing bands for the majority of non-LBT applications.

30. The Commission also recognized that some body worn devices may require higher power and greater bandwidth, such as the glucose monitoring devices manufactured by one manufacturer that are now operating in the core band under a waiver. Thus, the Commission decided to also allow non-LBT MedRadio devices using a maximum of 25 microwatts EIRP to operate at 401.85–402 MHz at the upper end of the lower wing band. The Commission determined that its decision would facilitate the transition of such devices now operating under waivers out of the core band, and into the new MedRadio wing bands. The Commission also noted that permitting the higher power and bandwidth would also provide flexibility for other manufacturers designing medical devices in these bands.

31. *Unwanted emissions.* The Commission retained without modification the existing in-band and out-of-band emission limits for the MedRadio core band frequencies at 402–405 MHz. For the new MedRadio wing bands at 401–402 MHz and 405–406 MHz, the Commission adopted an emission mask having the same form as the emission mask that already exists for the core band, but modified to apply over the narrower 100 kilohertz maximum authorized emission bandwidth of the wing band. Thus, the Commission required that emissions from devices operating within the MedRadio wing bands more than 50 kilohertz away from the center frequency of a transmission be attenuated below the actual transmitter output power by at least 20 dB. In addition, it required emissions 100 kilohertz or less below 401 MHz, or above 406 MHz, to be attenuated below the maximum permitted output power by at least 20 dB. Finally, for out-of-band emissions at more than 100 kilohertz outside the 401 MHz and 406 MHz MedRadio band edges, the Commission adopted generally the same field strength limits on emissions that presently apply to the core band.

32. The Commission declined to impose more restrictive limits on emissions from MedRadio wing band devices into the existing core band. The Commission said that under such an approach, which was recommended by one commenter, wing band devices would be burdened with more stringent limits on radiation into the core band as compared to core band devices. The Commission found no compelling reason to place wing band devices on such an unequal footing with core band devices, particularly if such a limit were to be set below the existing general emission limits contained in § 15.209 as suggested by one commenter. The Commission stated that it was confident that manufacturers of wing band devices are capable of designing their products to be compatible with and to protect core band devices, especially when both types of devices are used by the same patient. In addition, the Commission found that the emission limits it adopted would afford sufficient protection to satellite operations on frequencies below 401 MHz adjacent to the lower MedRadio wing band.

33. *RF safety and EIRP compliance.* The Commission retained the basic requirements in the current rules as they apply RF safety and EIRP compliance requirements for implanted devices. In addition, the Commission decided that, to the extent feasible, body-worn MedRadio devices shall be governed by the same requirements as other hand-held transmitting devices for the purposes of demonstrating compliance with RF safety and EIRP limits.

34. The Commission observed that it has another ongoing proceeding concerning RF exposure that would be better suited to address several other concerns expressed by some commenters. One issue involves whether and when open-area test sites or body-torso simulator measurements should be performed, and whether a 4 dB EIRP correction factor should be applied between implant and body-worn devices to account for the absorption of radio energy by body tissue that can be associated with implanted devices. A second issue involves whether unspecified ''other techniques'' (beyond the finite difference time domain (FDTD) technique cited in the existing rules) could be used for equipment authorization and RF exposure evaluation purposes. In view of the ongoing RF safety proceeding, the Commission declined to make any further modifications in this Report and Order.

35. *Disposition of Biotronik and DexCom Waivers.* The Commission noted that it had previously granted waivers to two device manufacturers (Biotronik and DexCom) that permit the manufacture and marketing in the United States of certain models of cardiac and diabetic therapy devices that do not possess the LBT frequency monitoring capability required by the present MICS rules for the core band at 402–405 MHz. Both waivers were stated to be valid for one year from the effective date of the final MedRadio rules adopted in this proceeding.

36. With respect to the *Biotronik Waiver,* the Commission found that the technical parameters of the authorized cardiac devices would now be encompassed within the provisions of the new MedRadio rules adopted herein—which provide for non-LBT operation by low power, low duty cycle implants operating between 403.5–403.8 MHz in the 402–405 MHz core band. Consequently, the Commission found that *Biotronik Waiver* would be rendered moot upon the effective date of the MedRadio rules adopted in this Report and Order.

37. With respect to the *DexCom Waiver,* the Commission found that the covered devices did not comply with the new MedRadio rules. It thus decided to extend the waiver term for four years from the effective date of the MedRadio rules adopted herein. The Commission stated that this extended term should provide DexCom with sufficient time to come into compliance with the new MedRadio rules and to obtain the required FDA approval. The Commission also found that continued operation of the DexCom non-LBT devices in the core band, particularly at the higher power levels they use, could in the long term prove problematic for other rules-compliant devices—especially those used for life-critical applications—as the numbers of these types of devices grow. Further, the Commission also observed that the wing bands provide adequate spectrum for both LBT and non-LBT body-worn devices and that DexCom's devices may reasonably be accommodated under the new MedRadio rules for these bands. In declining to extend the waiver for 5 years as requested by DexCom, the Commission stated that it was not persuaded that the relatively small move in operating frequency, while maintaining emission bandwidth, power and duty cycle specifications, would require 5 additional years. Thus, the Commission encouraged DexCom to transition to the newly designated spectrum as soon as practicable.

Final Regulatory Flexibility Analysis

38. As required by the Regulatory Flexibility Act (RFA),[1] an Initial Regulatory Flexibility Analysis (IFRA) was incorporated in the *Notice of Proposed Rulemaking and Notice of Inquiry and Order* (*MedRadio NPRM*) in ET Docket No. 06–135.[2] The Commission sought written public comment on the proposals in the *MedRadio NPRM,* including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

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

39. The Report and Order establishes the Medical Device Radiocommunication Service (MedRadio) under part 95 of the Commission's rules. This new service will incorporate the existing Medical Implant Communications Service (MICS) ''core'' band at 402–405 MHz, and include two megahertz of newly designated spectrum in the adjacent ''wing'' bands at 401–402 MHz and 405–406 MHz. Altogether, the MedRadio Service will provide a total of five megahertz of contiguous spectrum for advanced wireless medical radiocommunication devices to be used for diagnostic and therapeutic purposes in humans. Among other benefits, the MedRadio Service will accommodate the operation of body-worn as well as implanted medical devices, including those using either LBT or non-LBT spectrum access methods, in designated portions of the 401–406 MHz band.

40. Significant advances in wireless implanted and body-worn medical technologies are revolutionizing treatment for a wide variety of medical conditions and, even more fundamentally, creating new health care models serving to improve quality of life for all Americans. As demonstrated by the comment record in this proceeding, implanted and body-worn medical devices that rely upon wireless technologies are being used even today to treat a variety of cardiac and diabetic conditions. For example, wireless implanted cardiac devices serve as defibrillators and pacemakers without the need for external wired connections; while other radio-equipped devices, such as blood glucose monitors and insulin pumps, support more timely treatment for diabetic patients and allow physicians to wirelessly retrieve data and then make operating parameter adjustments with greater ease and accuracy than with the more traditional wired connection technologies. Some examples of newer generations of devices that could benefit from the use of wireless technologies include implanted vagus nerve stimulators that send electric pulses to the brain to treat severe chronic depression, and deep brain stimulators used to treat tremors related to Parkinson's disease.[3] Such advances have the potential to significantly improve the quality of life and sophistication of therapy for countless Americans living with a variety of medical conditions; and, in turn, could result in lower medical costs and extend the time between hospital visits and surgical procedures.

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

41. There were no comments filed that specifically addressed the rules and policies proposed in the IFRA.

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

42. 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.[4] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[5] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[6] 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.[7]

43. Nationwide, there are a total of approximately 22.4 million small businesses, according to SBA data.[8] A ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.''[9] Nationwide, as of 2002, there were approximately 1.6 million small organizations.[10] 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.''[11] Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States.[12] We estimate that, of this total, 84,377 entities were ''small governmental jurisdictions.''[13] Thus, we estimate that most governmental jurisdictions are small.

44. *Personal Radio Services.* The Medical Device Radio Communications Service are being placed 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 and covers a broad range of uses.[14] Many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the fact that licensing of operation under part 95 is accomplished by rule (rather than by issuance of individual license), and due to the shared nature of the spectrum utilized by some 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

[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 1966 (SBREFA), Public Law 104–121, Title II, 110 Stat. 857 (1996).

[2] Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401–402 and 405–406 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 06–135, RM–11271, *Notice of Proposed Rulemaking and Notice of Inquiry and Order,* 21 FCC Rcd 8164 (2006).

[3] Id.

[4] 5 U.S.C. 603(b)(3).

[5] 5 U.S.C. 601(6).

[6] 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).

[7] Small Business Act, 15 U.S.C. 632 (1996).

[8] *See* SBA, Programs and Services, SBA Pamphlet No. CO–0028, at page 40 (July 2002).

[9] 5 U.S.C. 601(4).

[10] Independent Sector, The New Nonprofit Almanac & Desk Reference (2002).

[11] 5 U.S.C. 601(5).

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

[13] 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.*

[14] 47 CFR part 90.

definition that might be directly affected by the proposed rules.

45. The Commission notes, however, that the designation for the two megahertz of spectrum for the Medical Device Radio Communications Service would be limited to use by medical implant and body-worn medical devices and, thus, would not be shared with other non-Federal Governmental uses. To date, there are only a small number of manufacturers (i.e., less than ten—as few as five) that produce these devices, and FDA approval must be secured before such devices are brought to market. Due to the stringent FDA approval requirements, the small number of existing medical device manufacturers tends to focus very narrowly on this highly specialized market niche.

46. *Wireless Communications Equipment Manufacturers.* The Census Bureau does not have a category specific to medical device radiocommunication manufacturing. The appropriate category is that for wireless communications equipment manufacturers. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees.[15] According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year. Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999. Thus, under this size standard, the majority of firms can be considered small.[16]

47. *Wireless Service Providers.* The SBA has developed a small business size standard for wireless firms within the two broad economic census categories of ''Paging'' [17] and ''Cellular and Other Wireless Telecommunications.'' [18] 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. [19] Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more.[20] 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.[21] Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more.[22] Thus, under this second category and size standard, the majority of firms can, again, be considered small.

48. *Public Safety Radio Services.* Public Safety radio services include police, fire, local government, forestry conservation, highway maintenance, and emergency medical services.[23] 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 entities [24] 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.[25]

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

49. The Commission is using the licensing approach for the entire 401–406 MHz MedRadio band that is identical to that used for the existing MICS band at 402–405 MHz. Thus, rather than require individual transmitter licensing, the Commission authorizes operation by rule within the Citizens Band (CB) Radio Service under part 95 of our Rules and pursuant to Section 307(e) of the Communications Act.[26] Licensing will be accomplished through adherence to applicable technical standards and other operating rules (unlicensed operations). The Commission concludes that this approach is beneficial because it would minimize the administrative burden on prospective licensees as compared with an individual licensing scheme.

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

50. 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

[15] NAICS code 334220.

[16] NAICS code 11210.

[17] 13 CFR 121.201, NAICS code 517211.

[18] 13 CFR 121.201, NAICS code 517212.

[19] 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).

[20] *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.''

[21] 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).

[22] *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.''

[23] 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 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.

[24] 47 CFR 1.1162.

[25] 5 U.S.C. 601(5).

[26] *See* Medtronic Petition at i, 16, and Appendix A, at proposed § 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.

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.[27]

51. In the Report and Order the Commission established a new Medical Device Radiocommunication Service (MedRadio Service) under part 95, which will encompass all medical devices permitted to operate in the 401–406 MHz band. It sought comment on the options concerning whether and how the five megahertz of spectrum that would comprise this MedRadio band could be divided among the evolving varieties of both implanted and body-worn medical transmitters, including low-power, low-duty-cycle (LPLDC) devices that do not employ ''listen-before-talk'' (LBT) frequency monitoring spectrum access techniques.

52. *Report to Congress:* The Commission will send a copy of the Report and Order, including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act.[28] In addition, the Commission will send a copy of the Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA.

Ordering Clauses

53. Pursuant to the authority contained in Sections 4(i), 301, 302, 303(e), 303(f) and 303(r) of the Communications Act of 1934, as amended, 47 USC Sections 154(i), 301, 302, 303(e), 303(f) and 303(r), this Report and Order *is adopted* and parts 1, 2 and 95 of the Commission's Rules *are amended* as set forth in Final Rules effective 90 days after publication in the **Federal Register.**

54. The Commission grants in part, consistent with the terms of this order, DexCom, Inc.'s request for extension of waiver, and otherwise *deny* the request in all other respects.

55. ET Docket No. 03–92 *is terminated.*

56. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis in Appendix C, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects

47 CFR Part 1

Administrative practice and procedure.

47 CFR Parts 2 and 95

Communications equipment, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 1, 2, and 95 to read as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 15 U.S.C. 79 *et seq.*; 47 U.S.C. 151, 154(i), 154(j), 155, 157, 225, 303(r), and 309.

■ 2. Section 1.1307 is amended by revising the fourth sentence in paragraph (b)(2) to read as follows:

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

* * * * *

(b) * * *

(2) * * * Equipment authorized for use in the Medical Device Radiocommunication Service (MedRadio) as a medical implant or body-worn transmitter (as defined in Appendix 1 to Subpart E of part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in § 2.1093 of this chapter by finite difference time domain computational modeling or laboratory measurement techniques.

* * *

* * * * *

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

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

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

■ 4. Section 2.106, the Table of Frequency Allocations, is amended as follows:

■ a. Revise page 24.

■ b. In the list of United States (US) footnotes, revise footnote US345.

The revisions read as follows:

§ 2.106 Table of Frequency Allocations.

* * * * *

BILLING CODE 6712–01–P

[27] *See* 5 U.S.C. 603(c).

[28] *See* 5 U.S.C. 801(a)(1)(A).

399.9-400.05 MOBILE-SATELLITE (Earth-to-space) 5.209 5.224A RADIONAVIGATION-SATELLITE 5.222 5.224B 5.260 5.220	399.9-400.05 MOBILE-SATELLITE (Earth-to-space) US319 US320 RADIONAVIGATION-SATELLITE 5.260		Satellite Communications (25)
400.05-400.15 STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz) 5.261 5.262	400.05-400.15 STANDARD FREQUENCY AND TIME SIGNAL-SATELLITE (400.1 MHz) 5.261		
400.15-401 METEOROLOGICAL AIDS METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) 5.208A 5.209 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.262 5.264	400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 METEOROLOGICAL-SATELLITE (space-to-Earth) MOBILE-SATELLITE (space-to-Earth) US319 US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264	400.15-401 METEOROLOGICAL AIDS (radiosonde) US70 MOBILE-SATELLITE (space-to-Earth) US319 US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264	Satellite Communications (25)
401-402 METEOROLOGICAL AIDS SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US345 US384	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US345 US384	MEDRadio (95I)
402-403 METEOROLOGICAL AIDS EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) Fixed Mobile except aeronautical mobile	402-403 METEOROLOGICAL AIDS (radiosonde) US70 EARTH EXPLORATION-SATELLITE (Earth-to-space) METEOROLOGICAL-SATELLITE (Earth-to-space) US345 US384	402-403 METEOROLOGICAL AIDS (radiosonde) US70 Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US345 US384	
403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US345 G6	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US345	
406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267	406-406.1 MOBILE-SATELLITE (Earth-to-space) 5.266 5.267		Maritime (80) Aviation (87) Personal Radio (95)
406.1-410 FIXED MOBILE except aeronautical mobile RADIO ASTRONOMY 5.149	406.1-410 FIXED US13 MOBILE RADIO ASTRONOMY US74 US117 G5 G6	406.1-410 RADIO ASTRONOMY US74 US13 US117	Private Land Mobile (90)

BILLING CODE 6712–01–C

* * * * *

United States (US) Footnotes

* * * * *

US345 In the band 401–406 MHz, the mobile, except aeronautical mobile, service is allocated on a secondary basis and is limited to, with the exception of military tactical mobile stations, Medical Device Radiocommunication Service (MedRadio) operations. MedRadio stations are authorized by rule on the condition that harmful interference is not caused to stations in the meteorological aids, meteorological-satellite, and Earth exploration-satellite services, and that MedRadio stations accept interference from stations in the meteorological aids, meteorological-satellite, and Earth exploration-satellite services.

* * * * *

■ 5. Section 2.1093 is amended by revising paragraph (c) to read as follows:

§ 2.1093 Radiofrequency radiation exposure evaluation: portable devices.

* * * * *

(c) Portable devices that operate in the Cellular Radiotelephone Service, the Personal Communications Service (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services, the Specialized Mobile Radio Service, the 4.9 GHz Band Service, the Wireless Medical Telemetry Service (WMTS) and the Medical Device Radiocommunication Service (MedRadio), authorized under subpart H of part 22 of this chapter, parts 24, 25, 26, 27, 80 and 90 of this chapter, subparts H and I of part 95 of this chapter, and unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under subparts D and E, 15.253, 15.255 and 15.257 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in 1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section as part of their application. Technical information showing the basis for this statement must be submitted to the Commission upon request.

* * * * *

■ 6. Section 2.1204 is amended by revising 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 or a medical body-worn transmitter as defined in part 95, granted entry into the United States or is a control transmitter associated with such an implanted or body-worn 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 Device Radiocommunication Service (MedRadio) 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 or on whom the medical body-worn transmitter is applied.

* * * * *

PART 95—PERSONAL RADIO SERVICES

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

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

■ 8. Section 95.401 is amended by revising paragraph (d) to read as follows:

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

* * * * *

(d) The Medical Device Radiocommunication Service (MedRadio)—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 and body-worn medical devices. The rules for this service are contained in subpart I of this part.

* * * * *

■ 9. Section 95.601 is amended by revising the last sentence to read as follows:

§ 95.601 Basis and purpose.

* * * The Personal Radio Services are the GMRS (General Mobile Radio Service)—subpart A, the Family Radio Service (FRS)—subpart B, the R/C (Radio Control Radio Service)—subpart C, the CB (Citizens Band Radio Service)—subpart D, the Low Power Radio Service (LPRS)—subpart G, the Wireless Medical Telemetry Service (WMTS)—subpart H, the Medical Device Radiocommunication Service (MedRadio)—subpart I, the Multi-Use Radio Service (MURS)—subpart J, and Dedicated Short-Range Communications Service On-Board Units (DSRCS–OBUs)—subpart L.

■ 10. Section 95.603 is amended by revising paragraph (f) to read as follows:

§ 95.603 Certification required.

* * * * *

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

* * * * *

■ 11. Section 95.605 is revised to read as follows:

§ 95.605 Certification procedures.

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, 218–219 MHz Service, LPRS, MURS, or MedRadio Service following the procedures in part 2 of this chapter. Dedicated Short-Range Communications Service On-Board Units (DSRCS–OBUs) must be certified in accordance with subpart L of this part and subpart J of part 2 of this chapter.

■ 12. Section 95.628 is revised to read as follows:

§ 95.628 MedRadio transmitters.

(a) *Frequency monitoring.* Except as provided in (b) of this section, all MedRadio programmer/control transmitters operating in the 401–406 MHz band must operate under the control of a monitoring system that incorporates a mechanism for monitoring the channel or channels that the MedRadio system devices intend to occupy. The monitoring system antenna shall be the antenna normally used by the programmer/control transmitter for a communications session. Before the monitoring system of a MedRadio programmer/control transmitter initiates a MedRadio communications session, the following access criteria must be met:

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

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

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

(4) If no signal in a MedRadio channel above the monitoring threshold power level is detected, the MedRadio programmer/control transmitter may initiate a MedRadio communications session involving transmissions to and from a medical implant or medical body-worn device on that channel. The MedRadio communications session may continue as long as any silent period between consecutive data transmission bursts does not exceed 5 seconds. If a channel meeting the criteria in paragraph (a)(3) of this section is unavailable, the channel with the lowest ambient power level may be accessed.

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

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

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

(iii) In the event that this alternate channel provision is not used by the MedRadio system or if the criteria in paragraphs (a)(5)(i) and (ii) are not met, a channel must be selected using the access criteria specified in paragraphs (a)(1) through (a)(4) of this section.

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

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

(ii) *MedRadio channel*—Any continuous segment of spectrum in the MedRadio band that is equal to the

emission bandwidth of the device with the largest bandwidth that is to participate in a MedRadio communications session.

Note to paragraph (a)(6)(ii): The rules do not specify a channeling scheme for use by MedRadio systems.

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

(b) *Exceptions to frequency monitoring criteria.* MedRadio devices or communications sessions that meet any one of the following criteria are not required to use the access criteria set forth in paragraph (a) of this section:

(1) MedRadio communications sessions initiated by a medical implant event.

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

(3) MedRadio devices operating in the 401.85–402 MHz band, provided that the transmit power is not greater than 25 microwatts EIRP and the duty cycle for such transmissions does not exceed 0.1%, based on the total transmission time during a one-hour interval.

(4) MedRadio devices operating with a total emission bandwidth not exceeding 300 kHz centered at 403.65 MHz, provided that the transmit power is not greater than 100 nanowatts EIRP and the duty cycle for such transmissions does not exceed 0.01%, based on the total transmission time during a one-hour interval.

(c) *Operating frequency.* MedRadio stations authorized under this part may operate on frequencies in the 401–406 MHz band as follows provided that the out-of-band emissions are attenuated in accordance with § 95.635:

(1) MedRadio stations associated with medical implant devices, which incorporate a frequency monitoring system as set forth in paragraph (a) of this section, may operate on any of the frequencies in the 401–406 MHz band.

(2) MedRadio stations associated with medical implant devices, which do not incorporate a frequency monitoring system as set forth in paragraph (a) of this section, may operate on any frequency in 401–402 MHz or 405–406 MHz bands, or at 403.65 MHz in the 402–405 MHz band.

(3) MedRadio stations associated with medical body-worn devices, regardless of whether a frequency monitoring system as set forth in paragraph (a) of this section is employed, may operate on any of the frequencies in the 401–402 MHz or 405–406 MHz bands.

(4) MedRadio stations that are used externally to evaluate the efficacy of a more permanent medical implant device, regardless of whether a frequency monitoring system as set forth in paragraph (a) of this section is employed, may operate on any of the frequencies in the 402–405 MHz band, provided that:

(i) Such external body-worn operation is limited solely to evaluating with a patient the efficacy of a fully implanted permanent medical device that is intended to replace the temporary body-worn device;

(ii) RF transmissions from the external device must cease following the patient evaluation period, which may not exceed 30 days, except where a health care practitioner determines that additional time is necessary due to unforeseen circumstances;

(iii) The maximum output power of the temporary body-worn device shall not exceed 200 nW EIRP; and

(iv) The temporary body-worn device must comply fully with all other MedRadio rules applicable to medical implant device operation in the 402–405 MHz band.

(d) *Authorized bandwidth.* The authorized bandwidth of the emission from a MedRadio station operating between 402–405 MHz shall not exceed 300 kHz, and no communications session involving MedRadio stations shall use more than a total of 300 kHz of bandwidth during such a session. The authorized bandwidth of the emission from a MedRadio station operating between 401–401.85 MHz or 405–406 MHz shall not exceed 100 kHz, and no communications session involving MedRadio stations shall use more than a total of 100 kHz of bandwidth during such a session. The authorized bandwidth of the emission from a MedRadio station operating between 401.85–402 MHz shall not exceed 150 kHz, and no communications session involving MedRadio stations shall use more than a total of 150 kHz of bandwidth during such a session.

Note to paragraph (d): This provision does not preclude full duplex or half duplex communications provided that the total amount of bandwidth utilized by all of the MedRadio channels employed in such a MedRadio communications session does not exceed 300 kHz in the 402–405 MHz band, or 100 kHz in the 401–402 MHz and 405–406 MHz bands.

(e) *Frequency stability.* Each transmitter in the MedRadio service must maintain a frequency stability of ±100 ppm of the operating frequency over the range:

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

(2) 0° C to 55° C in the case of MedRadio programmer/control transmitters and MedRadio body-worn transmitters.

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

(g) *Measurement procedures.* (1) MedRadio transmitters shall be tested for frequency stability, radiated emissions and EIRP limit compliance in accordance with paragraphs (g)(2) and (g)(3) of this section.

(2) Frequency stability testing shall be performed over the temperature range set forth in (e) of this section.

(3) Radiated emissions and EIRP limit measurements limit may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Power measurements for transmissions by stations authorized under this section may be made either in accordance with a Commission-approved peak power technique, or the following. Peak transmit power must be measured over any interval of continuous transmission using instrumentation calibrated in terms of an rms-equivalent voltage. The measurement results shall be properly adjusted for any instrument limitations, such as detector response times, limited resolution bandwidth capability when compared to the emission bandwidth, sensitivity, etc., so as to obtain a true peak measurement for the emission in question over the full bandwidth of the channel.

(i) For a transmitter intended to be implanted in a human body, radiated emissions and EIRP measurements for transmissions by stations authorized under this section may be made in accordance with a Commission-approved human body simulator and test technique. A formula for a suitable tissue substitute material is defined in OET Bulletin 65 Supplement C (01–01).

■ 13. Section 95.631 is amended by revising paragraph (h) to read as follows:

§ 95.631 Emission types.

* * * * *

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

* * * * *

■ 14. Section 95.633 is amended by revising paragraph (e) to read as follows:

§ 95.633 Emission bandwidth.

* * * * *

(e) For transmitters in the MedRadio Service:

(1) For stations operating in 402–405 MHz, the maximum authorized emission bandwidth is 300 kHz. For stations operating in 401–401.85 MHz or 405–406 MHz, the maximum authorized emission bandwidth is 100 kHz, and stations operating in 401.85–402 MHz, the maximum authorized emission bandwidth is 150 kHz.

(2) Lesser emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635. *See* §§ 95.628(g) and 95.639(f) regarding maximum transmitter power and measurement procedures.

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

* * * * *

■ 15. Section 95.635 is amended by revising the table to paragraph (b), and by revising paragraph (d) to read as follows:

§ 95.635 Unwanted radiation.

* * * * *

(b) * * *

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

* * * * *

(d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following: (paragraphs (d)(1) through (d)(5) pertain to MedRadio transmitters operating in the 402–405 MHz band; paragraphs (d)(6) through (d)(10) pertain to MedRadio transmitters operating in the 401–402 MHz or 405–406 MHz bands).

(1) Emissions from a MedRadio transmitter more than 250 kHz outside of the 402–405 MHz band shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
30–88	100	3
88–216	150	3
216–960	200	3
960 and above	500	3

Note—At band edges, the tighter limit applies.

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

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

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

(5) Emissions 250 kHz or less that are above or below the 402–405 MHz band will be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak

detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

(6) Emissions from a MedRadio transmitter operating in the 401–402 MHz or 405–406 MHz bands that are more than 100 kHz outside of either the 401–402 MHz or 405–406 MHz bands, and all emissions from such transmitter in the band 406.000–406.100 MHz shall be attenuated to a level no greater than the following field strength limits:

Frequency (MHz)	Field strength (μV/m)	Measurement distance (m)
30–88	100	3
88–216	150	3
216–960	200	3
960 and above	500	3

Note—At band edges, the tighter limit applies.

(7) The emission limits shown in paragraph (d)(6) are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz. *See also* § 95.605.

(8) The emissions from a MedRadio transmitter operating in the MedRadio bands (between 401–402 MHz or 405–406 MHz) must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.

(9) Emissions between 401–401.85 MHz or 405–406 MHz within the MedRadio bands that are more than 50 kHz away from the center frequency of the spectrum the transmission is intended to occupy (or more than 75 kHz away from the center frequency of MedRadio transmitters operating between 401.85–402 MHz) shall be attenuated below the transmitter output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

(10) Emissions 100 kHz or less below 401 MHz or above 406 MHz shall be attenuated below the maximum permitted output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

* * * * *

■ 16. Section 95.639 is amended by revising paragraph (f) to read as follows:

§ 95.639 Maximum transmitter power.

* * * * *

(f) In the MedRadio Service for transmitters that are not excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the maximum radiated power in any 300 kHz bandwidth by MedRadio transmitters operating at 402–405 MHz, or in any 100 kHz bandwidth by MedRadio transmitters operating at 401–402 MHz or 405–406 MHz shall not exceed 25 microwatts EIRP. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 402–405 MHz shall not exceed 100 nanowatts EIRP confined to a maximum total emission bandwidth of 300 kHz centered at 403.65 MHz. For transmitters that are excepted under § 95.628(b) from the frequency monitoring requirements of § 95.628(a), the power radiated by any station operating in 401–401.85 MHz or 405–406 MHz shall not exceed 250 nanowatts EIRP in any 100 kHz bandwidth and in 401.85–402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. *See* §§ 95.633(e). The antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization. Compliance with these EIRP limits may be determined as set forth in § 95.628(g).

* * * * *

■ 17. Section 95.649 is revised to read as follows:

§ 95.649 Power capability.

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

■ 18. Section 95.651 is revised to read as follows:

§ 95.651 Crystal control required.

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

■ 19. Appendix 1 to Subpart E of Part 95—Glossary of Terms is amended by removing the definition of ''Medical Implant Communications Service (MICS) transmitter'', ''MICS programmer/control transmitter'' and ''MICS''; and by revising the definitions of ''EIRP'', ''Medical implant transmitter''; and by adding the definitions of ''Medical body-worn device'', ''Medical body-worn transmitter'', ''MedRadio programmer/control transmitter'', ''MedRadio Service'' and ''MedRadio transmitter'' in alphabetical order to read as follows:

APPENDIX 1 TO SUBPART E OF PART 95—GLOSSARY OF TERMS

* * * * *

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

* * * * *

Medical body-worn device. Apparatus that is placed on or in close proximity to the human body (*e.g.,* within a few centimeters) for the purpose of performing diagnostic or therapeutic functions.

Medical body-worn transmitter. A MedRadio transmitter intended to be placed on or in close proximity to the human body (*e.g.,* within a few centimeters) used to facilitate communications with other medical communications devices for purposes of delivering medical therapy to a patient or collecting medical diagnostic information from a patient.

* * * * *

Medical implant transmitter. A MedRadio transmitter in which both the antenna and transmitter device are designed to operate within a human body for the purpose of facilitating communications from a medical implant device.

MedRadio programmer/control transmitter. A MedRadio transmitter that operates or is designed to operate outside of a human body for the purpose of communicating with a receiver, or for triggering a transmitter,

connected to a medical implant device or to a medical body-worn device used in the MedRadio Service; and which also typically includes a frequency monitoring system that initiates a MedRadio communications session.

MedRadio Service. Medical Device Radiocommunication Service.

MedRadio transmitter. A transmitter authorized to operate in the MedRadio service.

* * * * *

■ 20. Revise Subpart I to read as follows:

Subpart I—Medical Device Radiocommunication Service (MedRadio)

Sec.

Subpart I—Medical Device Radiocommunication Service (MedRadio)

§ 95.1201 Eligibility.

Operation in the MedRadio service is permitted by rule and without an individual license issued by the FCC. Duly authorized health care professionals are permitted to operate MedRadio transmitters. Persons may also operate MedRadio transmitters to the extent the transmitters are incorporated into implanted or body-worn medical devices that are used by the person at the direction of a duly authorized health care professional; this includes medical devices that have been implanted in that person or placed on the body of that person by or under the direction of a duly authorized health care professional. Manufacturers of medical devices that include MedRadio transmitters, and their representatives, are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MedRadio transmitter. The term ''duly authorized health care professional'' means a physician or other individual authorized under state or federal law to provide health care services. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

§ 95.1203 Authorized locations.

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

§ 95.1205 Station identification.

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

§ 95.1207 Station inspection.

Any non-implanted MedRadio transmitter must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted or body-worn MedRadio transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

§ 95.1209 Permissible communications.

(a) Except for the purposes of testing and for demonstrations to health care professionals, MedRadio programmer/control transmitters may transmit only non-voice data containing operational, diagnostic and therapeutic information associated with a medical implant device or medical body-worn device that has been implanted or placed on the person by or under the direction of a duly authorized health care professional.

(b) Except as provided in § 95.628(b) no MedRadio implant or body-worn transmitter shall transmit except in response to a transmission from a MedRadio programmer/control transmitter or in response to a non-radio frequency actuation signal generated by a device external to the body with respect to which the MedRadio implant or body-worn transmitter is used.

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

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

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

§ 95.1211 Channel use policy.

(a) The channels authorized for MedRadio 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) To reduce interference and make the most effective use of the authorized facilities, MedRadio transmitters must share the spectrum in accordance with § 95.628.

(c) MedRadio 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. MedRadio stations must accept any interference from stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meterological Satellite, or Earth Exploration Satellite Services.

§ 95.1213 Antennas.

No antenna for a MedRadio transmitter shall be configured for permanent outdoor use. In addition, any MedRadio antenna used outdoors shall not be affixed to any structure for which the height to the tip of the antenna will exceed three (3) meters (9.8 feet) above ground.

§ 95.1215 Disclosure policies.

Manufacturers of MedRadio transmitters must include with each transmitting device the following statement:

''This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) 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 stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog

and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.''

§ 95.1217 Labeling requirements.

(a) MedRadio programmer/control 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.''

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

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

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

§ 95.1219 Marketing limitations.

Transmitters intended for operation in the MedRadio Service may be marketed and sold only for the permissible communications described in § 95.1209.

§ 95.1221 RF exposure.

MedRadio medical implant or medical body-worn transmitters (as defined in appendix 1 to subpart E of part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of implant devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request the submission of specific absorption rate measurement data.

[FR Doc. E9–11063 Filed 5–13–09; 8:45 am]

BILLING CODE 6712–01–C

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 09–989; MB Docket No. 09–33; RM–11521]

Television Broadcasting Services; Derby, KS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking filed by Entravision Holdings, LLC, the permittee of station KDCU–DT, to substitute DTV channel 31 for post-transition DTV channel 46 at Derby, Kansas.

DATES: This rule is effective May 14, 2009.

FOR FURTHER INFORMATION CONTACT: Adrienne Y. Denysyk, Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 09–33, adopted April 27, 2009, and released April 30, 2009. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–478–3160 or via e-mail *http://www.BCPIWEB.com.* To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

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

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR Part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Kansas, is amended by adding DTV channel 31 and removing DTV channel 46 at Derby.

Federal Communications Commission.

Clay C. Pendarvis,

Associate Chief, Video Division, Media Bureau.

[FR Doc. E9–11207 Filed 5–13–09; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 040205043–4043–01]

RIN 0648–XP20

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-grouper Fishery of the South Atlantic; Closure of the 2009 Commercial Fishery for Black Sea Bass in the South Atlantic

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS closes the commercial fishery for black sea bass in the exclusive economic zone (EEZ) of the South Atlantic. NMFS has determined that the quota for the commercial