Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with sections 408(e) and 408(l)(6) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 18, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.601 is amended by revising paragraph (b) to read as follows:

§ 180.601 Cyazofamid; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the fungicide cyazofamid, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of cyazofamid, 4-chloro-2-cyano-*N,N*-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide and its metabolite CCIM, 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid, resulting from use of the pesticide under FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the table.

Commodity	Parts per million	Expiration/ revocation date
Basil, dried	144	12/31/14
Basil, fresh	12	12/31/14

* * * * *

[FR Doc. 2012–1815 Filed 1–26–12; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 95

[ET Docket No. 09–36; RM–11404; FCC 11–176]

Additional Spectrum for the Medical Device Radiocommunication Service

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document expands the Commission's Medical Device Radiocommunication (MedRadio) Service rules to permit the use of new wideband medical implant devices that employ neuromuscular microstimulation techniques to restore sensation, mobility, and other functions to paralyzed limbs and organs. These medical devices hold enormous promise to advance the state of medical care, lower health costs, and improve the quality of life for countless Americans. The rules will allow these new types of MedRadio devices to access 24 megahertz of spectrum in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands on a secondary basis.

DATES: Effective February 27, 2012.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Nicholas Oros, Office of Engineering and Technology, 202–418–063, *Nicholas.oros@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, ET Docket No. 09–36; RM 11404, FCC 11–176, adopted November 30, 2011 and released November 30, 2011. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best

Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.*

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

Summary of the Report and Order

1. In this Report and Order (R&O), the Commission expands the Medical Device Radiocommunication (MedRadio) Service under part 95 of the Commission's rules to permit the use of new wideband medical implant devices that employ neuromuscular microstimulation techniques to restore sensation, mobility, and other functions to paralyzed limbs and organs. These medical devices hold enormous promise to advance the state of medical care, lower health costs, and improve the quality of life for countless Americans. The rules adopted by the Commission will allow these new types of MedRadio devices to access 24 megahertz of spectrum in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands on a secondary basis.

2. The Commission's action is part of a larger effort to recognize and facilitate the significant advances in wireless medical technologies that are revolutionizing treatment for a wide variety of medical conditions and creating new health care models to benefit all Americans. 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. The devices that we expect to be deployed under the rules we adopt herein hold the promise of safer, less invasive, and more effective treatment options than those available under current medical practice.

3. The Wireless Medical Telemetry Service (WMTS) and MedRadio services, together with unlicensed medical applications developed and operated under our general part 15 rules, have supported countless vital therapeutic and diagnostic medical applications. The Commission recognizes, however, that the dynamic nature of medical technology means that our existing rules may need to evolve to keep pace with the newest cutting edge therapies. Thus, the Commission included in the *MedRadio Proceeding* a notice of inquiry seeking information in a broader context relating to future spectrum needs for wireless medical technologies. On September 5, 2007, the Alfred Mann Foundation for Scientific Research (AMF or Alfred Mann) filed a petition for rulemaking that serves as the basis of this proceeding.

4. In its petition, Alfred Mann asked the Commission to designate up to 24 megahertz of spectrum in the 413–457 MHz range to support new medical micro-power networks (MMNs) consisting of implantable neuromuscular microstimulation devices and associated external control units. Alfred Mann's petition was based on its research dating to 1989 on implantable medical devices to treat neurological injuries and disorders. Since 2005, AMF has conducted extensive work under the authority of an experimental license from the Commission to operate its devices in the 400–470 MHz band. Alfred Mann's wideband MMN equipment is designed to replace damaged nerve connections by performing functional electric stimulation (FES) to activate and monitor nerves and muscles in order to restore sensation, mobility, and other functions to nonfunctioning limbs and organs.

5. The work that AMF has done with the Veterans Administration and other hospitals under its experimental license has proven the potential benefits of MMNs. The Commission strongly believes that widespread MMN deployment can foster important advancements in medical care by, significantly improving the quality of life for the many Americans suffering from spinal cord injuries, traumatic brain injuries, and strokes. However, it also recognizes that MMNs represent a new type of radio communication which does not readily fit into any of the existing spectrum allocations. Because of the significant benefits that MMNs are poised to deliver, the Commission has concluded that the public interest warrants modifying its rules to allow their use. First, the Commission discussed the characteristics of MMN operations and concluded that this service is best accommodated by modifying and expanding our existing part 95 MedRadio rules. Second, it evaluated the frequency allocations necessary to support MMN operations and provide a secondary allocation in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands for use by MMNs as proposed. This means these devices cannot cause interference to and must accept interference from stations of a primary service. This restriction ensures that the potential for interference—*i.e.,* the only cost that would be imposed on other parties—is negligible. Finally, the Commission sets forth the service and technical rules that will allow MMNs operating on a secondary basis to share these bands with incumbent services.

7. The Commission's decision to allow MMNs to share spectrum with existing services supports the Commission's commitment to promoting efficient spectrum use to meet growing demand. In the March 2010 *National Broadband Plan,* the Commission underscored the importance of expanding opportunities for innovative spectrum access models made possible by advanced technologies. The Commission sought to promote the development of such technologies through its dynamic spectrum use technologies *Notice of Inquiry.* MMNs, which make use of advanced technology such as spectrum sensing, dynamic frequency selection, and notching out of interference signals to share spectrum with other services, demonstrate one such spectrum access model. These techniques will allow MMNs to use available spectrum to provide life-changing health benefits without impairing the ability of other licensed users in these frequency bands to continue providing service.

Medical Micro-Power Networks (MMNs)

8. In the *NPRM,* the Commission sought comments on authorizing MMN devices to operate in the 413–457 MHz band as an extension of our existing part 95 MedRadio rules. As a part 95 MedRadio service, MMNs would qualify for license-by-rule operation pursuant to Section 307(e) of the Communications Act (Act). Under this approach, medical devices would operate in the band on a shared, non-exclusive basis with respect to each other. AMF supports the license-by-rule framework and no one objects to this approach or suggests alternative licensing methods.

9. As discussed in the NPRM, the Commission will authorize MMN operations under the existing part 95 MedRadio rules. For MedRadio devices, the Commission determined that the license-by-rule approach minimized regulatory procedures and would facilitate more expeditious deployment of new generations of beneficial wireless medical devices. Also, MMNs share many characteristics with devices that operate in the existing MedRadio service. The core MedRadio band from 402–405 MHz is restricted to communication between an implanted medical device and an external

programmer/controller. This is the same architecture employed for AMF's MMNs. As with MedRadio implant devices, the MMN implant devices are sophisticated medical devices that are intended to be deployed by or under the direction of a duly authorized health care professional. The power levels proposed by AMF for MMN devices are on par with the power levels used by MedRadio devices. Additionally, both MedRadio devices and MMN systems are designed to operate in the 400 MHz frequency range, although MMNs require greater bandwidth than is available under the existing MedRadio rules. For the reasons provided, the Commission believes that the MedRadio license-by-rule framework is the best way to structure our MMN rules.

10. In the NPRM the Commission sought comment on a number of definitions that AMF proposed be added to the part 95 MedRadio Service rules for devices operating in the 413–457 MHz band. These definitions were for a Medical Micropower Network (MMN), MMN control transmitter, MMN implant transmitter, and MMN transmitter. The Commission adopted a single definition for MMN, as follows:

> *Medical Micropower Network* (MMN): An ultra-low power wideband network consisting of a MedRadio programmer/control transmitter and medical implant transmitters, all of which transmit or receive non-voice data or related device control commands for the purpose of facilitating functional electric stimulation, a technique using electric currents to activate and monitor nerves and muscles.

This definition tracks AMF's proposal in substance, with some word alterations to be consistent with the other MedRadio definitions. It is important to make these frequency bands available for medical applications such as AMF's MMNs that cannot be accommodated in other frequency bands and to avoid use of the band by non-medical devices or for non-medical purposes. The definition adopted by the Commission accomplishes this goal. Because the existing MedRadio definitions in the part 95 rules for MedRadio programmer/control transmitter, Medical implant transmitter, and MedRadio transmitter can also describe the functions of the MMN control transmitter, MMN implant transmitter, and MMN transmitter, respectively, the Commission will not adopt MMN-specific definitions for these devices.

11. The Commission declines to adopt the more expansive definitions proposed by Sienkiewicz and the Cleveland FES Center or to substantially deviate from the framework proposed in the NPRM. It recognizes that the existing programmer/control transmitter definition does not permit use of implanted programmer/control transmitters or the deployment of an MMN that functions without a programmer/control transmitter, as Sienkiewicz and the Cleveland FES Center have suggested should be permitted for MMNs. The record in this proceeding is largely based on AMF's MMN system, which uses an external programmer/control transmitter which implements a number of interference mitigation techniques to allow the MMN to share spectrum with other services in these bands and which has been subject to extensive testing. The Commission has no information at this time to determine whether an MMN without an external programmer/controller could mitigate the effects of interference and successfully coexist in these bands. Other use of these frequency bands such as for non-FES medical applications or allowing transmission of voice data is speculative at this point. No one has provided guidance on what alternative specifications would appropriately accommodate other uses while not compromising the potential of MMNs. Further modification to the rules may be readily sought if and when a need arises.

12. Based on this definition and the rules the Commission adopts under it, the Commission can be sure that all MMNs will be designed with sufficient interference mitigation techniques and design elements to be able to operate on a secondary basis under the Commission's part 95 rules. At the same time, and because it wants parties to be able to tap the vast potential MMN technologies have to transform lives and advance the state of medical care, the Commission rejected those comments that would have us bind our rules too tightly to AMF's specific equipment design. Because manufacturers may develop new MMN devices with different interference mitigation techniques, the Commission does not think it is appropriate to require that all MMN devices function in an identical fashion to AMF's devices. Future systems, may rely on technologies that have an even greater capability to reject interference than AMF's current design, and the Commission will evaluate individual devices as part of its equipment authorization process.

13. Finally, the Commission sought comments in the *NPRM* on the service and technical rules that would apply to medical devices in the 413–457 MHz band. The discussion generally followed the framework of the MedRadio Service rules with, for example, modified power and emission bandwidth requirements to accommodate the proposed MMNs. While the Commission did not include a separate appendix of proposed rules, the NPRM stated that the Commission was seeking comment on allowing additional spectrum to be used under the MedRadio Service in part 95 of the Commission's rules, referenced new rules that AMF had proposed in its filing, and discussed specific service and technical issues at length. For this reason parties have had ample opportunity to provide meaningful comments on the proposals, and the Commission rejected suggestions to the contrary. Because the Commission is including MMNs within the existing framework of the MedRadio Service, it will apply the existing MedRadio service and technical regulations to MMNs to the extent possible and only amend the rules in part 95, Subparts E and I, as necessary to distinguish between MMNs and other MedRadio devices. As observed in the NPRM, such an approach ''is desirable as it would maintain consistency with rules applicable to wireless medical devices, particularly for implanted and related therapeutic devices.''

Frequency Bands

14. Although the Commission concluded that it is appropriate to license MMNs as a MedRadio service, it does not follow that it is feasible for MMNs to operate on the existing MedRadio frequencies. This is because MMNs are different from existing MedRadio applications in important technical and design elements. For example, a typical MMN is expected to contain multiple implant devices, which will require the transmission of much more data than the MedRadio devices operating under the existing rules. Moreover, due to their small size, MMN implant devices must be even more energy efficient than typical MedRadio implants. This efficiency is achieved by using short transmissions, which necessitate the use of much wider bandwidth signals than the 300 kHz currently permitted in the existing MedRadio bands. This limit was put in place to maximize the number of medical devices that can use the 5 megahertz available in the 401–406 MHz band and is consistent with the operational needs of existing MedRadio applications. By contrast, MMNs are designed to operate with a 5 megahertz emission bandwidth. Thus, the current MedRadio frequencies are insufficient to support MMN operation.

15. *Decision.* Consistent with our proposal, the Commission will allocate the 24 megahertz of spectrum in four

segments of the 413–457 MHz band for MMN use on a secondary basis, *i.e.,* 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz. As described by AMF, the propagation characteristics of the 400 MHz band make it particularly well suited to host MMN devices, and the band is already used for other MedRadio implanted devices. Further, because these four band segments will allow for the wide bandwidth signals required to transmit large amounts of data in a short amount of time, they will provide the emission bandwidth that MMNs require. As explained, the Commission does not believe operation on a secondary basis will detrimentally impact the development or deployment of MMNs as they are designed to be able to operate on a secondary basis.

16. The Commission also concluded that allocating four band segments for MMN use is necessary to ensure that an MMN has sufficient spectrum to operate while avoiding causing interference to or receiving interference from primary users in the band. An MMN will occupy only one band segment at any given time. By having a variety of authorized frequency bands available and employing protocols that will allow MMNs to quickly migrate from band to band, an MMN licensee will be able to make robust use of the available spectrum and respond to changing spectrum conditions. In addition, the four band segments serve a mix of Federal and non-Federal use. By permitting MMN use of all four segments, the Commission will give MMNs more flexibility to operate in differing RF interference environments. Commenters expressed concern that heavy band use situations could render a particular frequency band unavailable to MMNs for extended periods of time. However, the Commission does not believe that such a possibility should categorically preclude us from allocating the four proposed frequency bands. Similarly, the fact that certain interference mitigation techniques might work in some situations but not in others is not a reason to prevent MMNs from being authorized to operate in all four frequency bands. Even in a worst-case situation, the Commission can expect that many patients with MMN implants will still be able to make effective use of at least one of the allocated frequency segments.

17. The Commission will implement this allocation by modifying footnote US345 to the Table of Allocations for the MedRadio service to add a secondary mobile, except aeronautical mobile, allocation for the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz frequency bands and renumbering this footnote as US64. This allocation will be in addition to the existing allocations in these four frequency bands and will be limited to use solely by MedRadio operations. The Commission is making this allocation through a footnote rather than a direct entry in the Table for consistency with the existing MedRadio allocation and to emphasize the limited nature of this allocation.

18. The Commission will place this footnote in both the Federal Table and non-Federal Table for each of these four frequency bands to allow use in a variety of settings such as in health care facilities operated by the Department of Veterans Affairs or the United States military, as well as non-Federal health care facilities. Even though this allocation will be both a Federal and non-Federal allocation, the Commission does not expect any changes in the primary use of any of these frequency bands. The 413–419 MHz band will continue to be used primarily for Federal mobile and space research services. The 451–457 MHz band will continue to be used primarily for non-Federal land mobile services. The 426–432 MHz and 438–444 MHz bands will continue to be shared by the Federal radiolocation service and the non-Federal Amateur service. Because MedRadio use of these bands will be on a secondary basis, MedRadio stations will not be allowed to cause interference to and must accept interference from primary services sharing the bands. Consequently, there is no reason for any changes to the current coordination procedures between FCC and NTIA for these frequency bands. NTIA will continue to manage the 413–419 MHz band, the FCC will continue to manage the 451–457 MHz band, and both agencies will continue to share management responsibilities of the 426–432 MHz and 438–444 MHz bands.

19. The Commission also notes that the spectrum it is adding to the MedRadio Service is allocated to similar services in both the United States Table and in all regions of the world in the International Table. Thus, the Commission believes that MMN devices designed to be compatible with U.S. radiocommunications services will be equally compatible with the services found elsewhere in the world. However, it is not aware of any other administrations that have made provisions for MMNs. Although individuals using MMNs should not encounter significantly different electromagnetic environments when traveling abroad, the use of MMNs may be restricted in other countries. The Commission finds that the benefits promised by MMNs as well as the ability for MMNs to coexist with the radiocommunications services already allocated internationally in the bands under consideration support our decision to adopt the proposed allocation.

20. The Commission rejected other frequency band suggestions made by commenters and find that they would not be suitable for MMN use. It rejected suggestions by the National Association for Amateur Radio (ARRL), the Land Mobile Communications Council (LMCC), the Enterprise Wireless Alliance (EWA), and Motorola that the WMTS bands are more appropriate for MMNs. In the MedRadio proceeding, the Commission stated that frequencies below 216 MHz and above 470 MHz are ''outside the range of spectrum generally considered to be the most suitable for propagation of radio signals within the human body.'' Because implanted MMN devices must operate with minimal power, efficient propagation of signals through the human body is extremely important for their operation. The WMTS bands from 608–614 MHz, 1395–1400 MHz, and 1429–1432 MHz are far above the suitable range for signal propagation in the human body. While the use of additional power might overcome the decreased propagation of signals in the human body in these bands as compared to the 400 MHz band, it appears that it is not practical to substantially increase the size of batteries in the MMN implant devices. In addition, the 608–614 MHz WMTS band is heavily used in medical facilities and could complicate reliable MMN service in such close proximity. The Commission therefore concludes that the WMTS bands are not a practical alternative for use by MMNs.

21. The Commission's NPRM envisioned, and AMF has designed, MMNs that are capable of operating on a secondary basis in frequency bands with existing, established incumbent use. Through the use of harmful interference mitigation techniques, operations on multiple frequency bands, and pre-established shutdown protocols in the event that no frequency bands are available, MMNs will be able to operate successfully in the lower 400 MHz band. The Commission is further encouraged by the fact that the MMN concept is not just theoretical: AMF has engaged in prototype development under an experimental license that it has held since January 2005 and in actual evaluation and testing in cooperation with Federal stakeholders. AMF notes that it has developed prototype programmer/controllers that

implement these interference mitigation techniques and points out that these techniques have been independently tested and shown to be effective against a wide range of potential interference signals.

22. AMF submitted interference analyses, test reports, and technical studies that it had commissioned to evaluate MMN use in the identified bands. These materials were the product of a process that began in August 2009, when AMF and the Joint Spectrum Center (JSC) (a field office within the U.S. Defense Spectrum Organization that provides spectrum planning and support for U.S. military interests) entered into a memorandum of agreement (MOA) for JSC to conduct a technical analysis to determine whether MMN devices could co-exist with incumbent government systems in the 413–457 MHz band.

23. Pursuant to the MOA, JSC directed a contractor, ITT, to collect, validate, and evaluate technical data regarding MMN devices and incumbent government systems. The resulting report (JSC Report) contained a theoretical analysis to evaluate the electromagnetic compatibility (EMC) of incumbent government system receivers in the presence of radiofrequency (RF) emissions from MMN transmitters and the EMC of MMN receivers of both the programmer/controller (P/C) and implanted microstimulator devices—in the presence of RF emissions from incumbent systems. The JSC reviewed the report and approved it for publication in October 2010.

24. The JSC Report concluded that, with respect to the MMN-to-government system interference potential, (1) ''relatively small [required separation distances] result from the low EIRP and duty cycle of the MMN transmitters combined with the low antenna heights of the MMN,'' and (2) MMN systems ''should be operationally compatible and not cause unacceptable interference into [incumbent government] systems currently authorized to operate in the 410–450 MHz band.''

25. In addition, AMF commissioned Aerospace Corporation (the operator of a federally funded research and development center and provider of comprehensive technical service to national security space programs) to conduct laboratory tests to determine whether MMNs could successfully operate in the presence of incumbent users. To evaluate the performance of the MMN network in the 413–457 MHz band, the Aerospace testers conducted a wired simulation of the frequency bands. Specifically they tested signals representing Federal mobile radio (data and voice), radar (ground and airborne), and the Enhanced Position Location Reporting System, as well as non-Federal amateur television. The tests specifically targeted four MMN interference mitigation techniques: spectral excising of narrowband incumbent signals; changing frequency bands without suspending critical functions; shutting down in a communication link loss scenario; and incumbent signal level sensing to avoid interference. The resulting report (Aerospace Report) concluded that the AMF MMN System performs according to its specifications and can successfully operate in presence of incumbent users.

26. The JSC Report and Aerospace Report offer detailed evaluations of specific interference scenarios involving a broad spectrum of incumbent operations backed up by testing with actual equipment. Based on these reports, the Commission concluded that the record demonstrates that MMNs can operate on a compatible secondary basis with primary Federal operations in the 413–419 MHz, 426–432 MHz, and 438–444 MHz band segments.

27. The Commission is also convinced that MMNs can operate on a compatible secondary basis with primary non-Federal operations. The findings of the JSC Report, which focused on Federal systems, and the simulations conducted by AMF and the Aerospace Corporation, which looked at a wider variety of high-powered signals, support this conclusion. In this regard, non-Federal fixed and land mobile radio systems in the 451–457 MHz frequency band use the same technologies as Federal fixed and land mobile radio systems in the 420–450 MHz frequency band. Moreover, the mitigation techniques that the Aerospace Report examined have broad applicability. For example a P/C that incorporates ''notching'' techniques could filter out a 100 kHz RPU signal from a BAS operator.

28. The Commission believes that the JSC Report, Aerospace Report, and associated materials filed by AMF are responsive to these concerns. In addition, because these materials provide extensive technical details about the interference mitigation techniques employed by AMF's MMN devices, the Commission disagrees with the contention of the Engineers for the Integrity of the Broadcast Auxiliary Service Spectrum (EIBASS) that AMF has provided insufficient technical details about its interference mitigating protocols.

29. A number of parties claim that incumbent operators could receive harmful interference from MMN devices. The Commission disagrees. Several factors serve to reduce any risk that MMNs could cause harmful interference. First, the JSC Report concluded that the MMN systems would not cause unacceptable interference into government systems in the 413–419 MHz, 426–432 MHz, and 438–444 MHz bands. Again, because the non-Federal land mobile systems in the 451–457 MHz are virtually identical to the types of government systems considered in the JSC Report, there is no basis for us to expect interference to non-Federal land mobile systems. Such non-Federal land mobile systems must overcome interference caused by the high-powered operations of other incumbents in the band. For this reason, they are well equipped to tolerate the presence of any signals they might receive from an MMN system operating at a much lower power. The Aerospace Report, which tested actual prototype MMN devices and concluded that incumbent services would not receive significant interference, further bolsters our conclusion. The Commission further notes that some commenters have rejected the likelihood of interference from MMN devices to their services which, like land mobile systems, operate at much higher powers than MMNs. Finally, the Commission adopts service rules that will require an MMN to switch to another frequency if it appears that there is an incumbent operating in close proximity.

30. The studies commissioned by AMF show that MMNs are able to function with a significant amount of interference from incumbent operations. As such, the Commission is not persuaded by those comments that claim that MMNs are incompatible with incumbent non-Government licensees. Incumbent systems that operate in the bands under consideration share the same high-powered operational attributes that MMNs have been specifically designed to tolerate.

31. To the extent that objections from commenters focus on the fact that a transmitter of a particular service may cause interference when operating in close proximity to an MMN device, commenters fail to acknowledge that the MMN system design anticipates such a scenario. There is no dispute that MMN devices may not be able to function in one or more of the four bands at a particular moment because of interference. AMF's MMN devices are capable of switching among the four different bands and are designed to operate on one band at a time, and the Aerospace Report found that this design feature worked as planned. Moreover, because MMNs are designed to operate in a variety of bands with a diverse set

of Government and non-Government users, a band that is rarely available for use in a particular place or at a specific time may be uncongested in other situations. Under this reasoning, the Commission is not troubled by EIBASS's claim that the tests submitted by AMF did not specifically consider RPU operations, a claim AMF refutes. EIBASS states that RPU broadcasts are distinct because they often employ a long duty cycle and postulates a scenario where extended RPU operations would take place at a health care facility. In such a case, the MMNs operating in that place and time would simply not be able to access the portion of the MedRadio band that is being used by the RPU operator.

32. Several parties argue that it would be inappropriate for us to permit medical devices—and MMNs in particular—to operate on a secondary basis. The Commission disagrees with parties that argue that it should never allocate spectrum to medical devices on a secondary basis. As a general matter, the Commission takes many factors into account in deciding whether a given service should operate with a primary or secondary status in a designated frequency band or even whether a device should operate on an unlicensed basis under part 15 of its rules. Each case is evaluated on its own merits. This is also true of our allocations for medical devices. At the present time, the Commission's rules allow medical devices to operate on a primary basis, on a secondary basis, and on an unlicensed basis. The Commission finds in this order that the characteristics of the MMN devices at issue here warrant operation on a secondary basis. The MMN devices that will be deployed under the rules that it adopted herein will be frequency agile and can switch to other frequency bands when interference occurs. Thus, the MMN devices will be designed with capabilities that enable them to share spectrum with primary services successfully. Rigorous testing has shown that MMN devices can perform as intended.

33. The Commission acknowledges that there may be instances when MMN devices cannot operate due to interference on all frequency bands. However, it also notes that AMF has accounted for this possibility by designing its MMN devices to shut down in a controlled, pre-planned manner that is designed to avoid harm to the patient or others if interference in all four frequency bands prevents successful reception of signals by the MMN system. The Commission rejects the notion that the potential for such a shutdown should categorically bar us from designating spectrum for MMNs and, thus, deny the benefits associated with these devices. The Food and Drug Administration (FDA), as part of its independent review process, will take into account these ''graceful shutdowns'' when it determines when and how MMN use can be prescribed. Further, the Commission will require that MMN devices be authorized under the direction of a duly authorized health care professional who will inform patients of the risks associated with MMN use, including ''graceful shutdowns.''

34. The Commission must balance the cost of allowing MMNs to operate on a secondary basis in these bands against the benefits that patients could potentially receive from their use. Given the extremely low risk of incumbent services suffering interference from MMNs and the yet lower risk of a harmful result from any such interference, the potential benefits of establishing a secondary allocation and adopting rules to allow MMN operation outweigh the slight risk to incumbent services. Because of the great potential of MMNs to improve the lives of people who suffer from a range of illnesses such as spinal cord injuries, traumatic brain injuries, strokes, and various neuromusculoskeletal disorders, the Commission recognizes the enormous potential benefit of allowing MMNs to become a reality. The benefits of making this secondary allocation and adopting rules to facilitate MMN operations therefore far exceed any potential costs.

35. Lastly, the Commission addressed several commenters' overarching concerns that new MedRadio applications must remain truly secondary—neither interfering with incumbent operations nor creating an expectation that MMNs must be protected from the types of interference that higher-powered primary uses may legitimately cause. The Commission fully intends that MMN devices will operate within the constraints of their secondary status, and it does not adopt here any limitations on the operations of incumbent primary services in these bands for the benefit of MMN operation. Because AMF has designed its MMNs to anticipate interference and to operate in a challenging spectrum environment, the Commission is confident that they will remain secondary in both rule and practice. The Commission also clarified that MMNs, the Amateur Radio Service, and the non-Federal radiolocation service—all of which operate under a secondary allocation in the 426–432 MHz and 438–444 MHz bands—will have equal status. Given that MMN devices are expected to implement measures to mitigate the effects of interference, it is reasonable to expect the MMN devices to tolerate some interference from the Amateur Service or to move to another frequency band as needed. As ARRL concedes, MMN devices are ''unlikely generally'' to cause interference to Amateur Radio communications in these bands.

Service and Technical Rules

36. In the NPRM the Commission asked about the service and technical rules that should apply to medical devices in the 413–457 MHz band. The discussion generally followed the framework of the existing MedRadio Service rules and proposed to modify specific rules, such as those pertaining to power and emission bandwidth requirements, to accommodate the proposed MMNs. The Commission also noted that the service and technical rules discussed in the NPRM were essentially consistent with recommendations made in the Alfred Mann petition.

37. The Commission adopted the overall approach proposed in the NPRM. Thus, rather than creating a new rule subpart for MMNs, it will only amend the service and technical rules contained in part 95 subparts E and I of its rules to the extent necessary. The Commission also adopted service and technical rules that are based on the research undertaken for AMF's MMN devices. This approach offers incumbent operators greater certainty as to the types and characteristics of MedRadio devices that may be deployed in the band and, because it is backed by extensive testing, provides greater certainty that MMNs and other new medical technologies will be able to thrive on a secondary basis in these frequencies. The Commission is confident that the state of medical radiocommunication technology will evolve and improve over time, as will mitigation techniques that maximize sharing potential on a secondary basis. Further development and testing of future generations of MMNs may allow us to adopt service rules that provide even greater flexibility while still protecting incumbent services. However, the service and technical rules it adopts here are appropriate based on the record before us today.

38. *Interference Mitigation.* Because MMNs will operate under the secondary MedRadio Service, they must be designed to function in the presence of signals from other services operating in the same frequency bands. The interference analysis, test reports, and technical studies that AMF submitted

have demonstrated that it is possible to build MMNs that are highly resistant to interference, and as technology continues to advance, the Commission believes it will be possible to build MMN devices that are even more capable of functioning in the presence of interference. To ensure future flexibility for equipment designers, the Commission will not require that MMNs include all of the types of interference mitigation techniques that AMF has employed in its MMN devices. Instead, the Commission will adopt the general requirement that P/C transmitters have the ability to operate in the presence of other users in the 413–457 MHz band, and it will incorporate several basic interference mitigation provisions into its rules. The Commission expects that MMN technology developed in the future will be at least as capable of co-existing with other services as the system AMF has demonstrated.

39. Regardless of the interference mitigation techniques employed, the Commission expects that there will be instances where MMNs will not be able to function in a particular frequency band because of a high level of interference from other stations. To provide a greater probability that an MMN will continue to function in the presence of interference, the Commission adopted the requirement that all MMNs be capable of operating in any of the four frequency bands and that they be able to switch to another frequency band when the band on which they are operating becomes unavailable due to interference. The Commission concludes that these requirements will not increase the cost of equipment unreasonably or be burdensome for manufacturers to meet. As AMF has noted, these four bands are nearly adjacent in frequency and thus incorporation of a multi-channel operating capability requires no significant change in antenna or transmitter design and ''imposes no undue economic burden.'' Only a single transmitter and one antenna are necessary to cover these four bands. Components to enable manufacturers of MMNs to meet this requirement should be readily available since equipment is currently designed to operate across the Federal mobile bands between 406.1 MHz and 450 MHz and non-Federal mobile bands between 450 MHz and 512 MHz. Thus, the Commission concluded that the improved robustness of MMNs that will result from these requirements will more than offset the expected minimal cost of implementing them.

40. The Commission also notes that AMF has proposed several rules regarding interference mitigation techniques for MMNs. These suggested rules are based on AMF's experience in building and testing MMN systems. Because of AMF's expertise in this area and the lack of input from other parties on this issue, the Commission is adopting technical provisions to add assurance that any MMN technology developed in the future will be able to operate successfully in the heavily used 413–457 MHz frequency range.

41. To be able to switch to another frequency band when an existing band becomes unavailable due to high levels of interference, it will be necessary for an MMN to be aware of the potential for interference in all four frequency bands. To that end, the Commission adopted the requirement suggested by AMF that the programmer/controller (P/C) of an MMN monitor all four available frequency bands. For the band in which the MMN is operating, the P/C must check at least once a second for interference so as to be able to switch frequency bands to avoid disabling amounts of interference. Because most of the potential interferers in these bands such as land mobile, BAS, and amateur stations, typically transmit far longer than one second, a once-a-second monitoring interval should be sufficient to detect interfering signals. The P/C must be capable of determining when either direction of the communication link between the P/C and the implanted devices is being degraded to the extent that communication is likely to be lost for more than 45 milliseconds. The Commission will require the P/C to move the MMN to another frequency band upon making this determination. It will also require the P/C to monitor the other frequency bands often enough such that when it must switch frequency bands it has determined which frequency band is available based on monitoring of that band during the two second period prior to switching. According to AMF, incorporating a requirement to monitor MMN channels prior to executing a channel change ''will not materially increase production costs.'' This is not surprising considering that radios now operating in these bands also have a requirement to monitor channels prior to transmitting on them and that the technology and techniques to accomplish spectrum monitoring in these bands are well established. Thus, the Commission concludes that the benefits of these monitoring requirements far outweigh the expected costs to comply.

42. Because the MMN devices operate with such low power, the Commission does not believe that they will cause interference to other stations sharing the same frequency bands. However, out of an abundance of caution it adopted one additional monitoring requirement to further reduce the risk of interference. The Commission will require the P/C to switch to another frequency band if during the monitoring of the occupied frequency band it determines that there is a received signal with power greater than −60 dBm in any 12.5 kHz bandwidth being used by the MMN device that persists for at least fifty milliseconds. A received signal of this strength is likely to be caused by a station in close proximity to the P/C. The Commission is using a measurement bandwidth of 12.5 kHz for this determination because this is the signal bandwidth used by all Federal land mobile stations. Non-Federal land mobile operations are currently undergoing a migration from using 25 kHz channels to 12.5 kHz channels, and consequently, in the near future the majority of licensees will also be limited to signal bandwidths of 12.5 kHz. The Commission chose this measurement bandwidth based on land mobile stations because they are the most numerous stations that will share these frequency bands with MMNs. This requirement should prevent the unlikely occurrence of interference from an MMN device to another service sharing the same frequency band.

43. There may occasionally be instances when MMNs may not be able to function because of high levels of interference in all four frequency bands. To account for these infrequent occurrences, the rules the Commission adopted will require that all MMN transmitters incorporate a programmable means to implement a system shutdown process in the event of a communication failure or on command from the P/C. Because MMNs are used to provide therapeutic benefits to patients, such as providing them with a means to move muscles that they would not otherwise be able to move, it is important that the Commission require the MMNs to incorporate a means to implement a pre-defined system shutdown process. The Commission believes that this requirement offers vital benefits to patients and is integral to the success of the MMN system design. Because MMNs are sophisticated electronic devices and the programming necessary to implement a system shutdown process should represent only a portion of the overall design costs, the Commission concludes that the benefits of a system shutdown requirement far outweigh any associated costs. The Commission will require that this shutdown process commence within 45

milliseconds after loss of the communication link or receipt of the shutdown command from the P/C.

44. *Contention Protocol Requirement.* In the NPRM, the Commission sought comment on a number of questions related to contention protocols, such as whether a contention protocol should be applied to MMN transmitting devices, what kinds of contention protocols should or should not be used, and how a contention protocol might be developed. A contention protocol would be aimed at allowing multiple MMN systems to share the specified frequency bands without causing interference to each other. This approach differs from the interference mitigation techniques that AMF's MMN devices employ. These techniques are designed to allow the MMNs to function in the presence of interference from other services sharing the same frequency bands. Commenters supported the idea of MMNs using a contention protocol, but no one specified a particular contention protocol that the Commission could adopt.

45. The Commission appreciates that requiring MMNs to use a common contention protocol would enable MMNs to more efficiently share the available spectrum. However, as no commenters have suggested a specific contention protocol, it cannot adopt a requirement for use of a specific contention protocol at this time. The Commission also will not require the development of a contention protocol by a particular date. Given the novelty of MMN technologies, the Commission is not able to predict when entities other than AMF will develop MMNs for use in these bands and therefore have no grounds to speculate on how and in what timeframe a contention protocol may be developed. The Commission does encourage manufacturers of MMN devices to cooperate in the development of a contention protocol so that the MMN devices may more effectively share the limited available spectrum. If, in the future, parties establish a specific contention protocol that they believe should be applied to these bands, they are welcome to file a Petition for Rulemaking to bring such information to our attention.

46. In the NPRM, the Commission also sought comment on using the listen-before-talk (LBT) approach of the existing MedRadio service rules to share spectrum between different MMNs. Under this approach, a transmitting device must monitor a frequency band for the presence of other MedRadio transmitters before beginning transmissions in that frequency band. If a signal with power above a certain threshold is detected, the transmitting device is not allowed to transmit in that frequency band. The Commission has adopted a similar requirement with a high power threshold (-60 dBm in a 12.5 kHz bandwidth) to help guard against the unlikely occurrence of interference from MMNs to other services sharing the same frequency band. Use of this high threshold will not be effective in facilitating MMN-to-MMN sharing because MMNs transmit such low power over a wide bandwidth. The Commission will not adopt a similar requirement with a lower LBT threshold because it would interfere with the functioning of the interference mitigation techniques employed by AMF's MMN devices. The MMN devices would not be able to determine whether a detected signal with a power above the LBT threshold is from another MMN or is a signal from another service sharing the same frequency band. Because MMNs should be designed to operate in the presence of a certain level of interference from other services operating in the same frequency band, not transmitting when signals above a lower LBT threshold are present would lead to MMNs not making use of the available spectrum effectively.

47. *Permissible Communications and Operator Eligibility.* In the NPRM, the Commission sought comment on restricting implant devices for use by persons only for diagnostic and therapeutic purposes and only to the extent that such devices have been provided to a human patient under the direction of a duly authorized health care professional. This requirement is present in our existing MedRadio rules and is consistent with how the Commission expects MMNs to be used. No one has raised an objection to this requirement. The Commission will therefore apply this restriction for MMNs.

48. The Commission also sought comment on prohibiting the medical implant programmer/controller (P/C) from relaying information to a receiver that is not included with a medical implant device. This prohibition is included in the existing MedRadio rules. The Commission will allow P/Cs in different MMNs to communicate with each other for the purposes of coordination of the use of the spectrum resource. This differs from our existing MedRadio rules, which prohibit controller-to-controller communication. The Commission expects that each MMN will use a spectrum band for short periods of time as is the case for AMF's MMNs. Because of this, multiple MMNs should be able to share a frequency band without causing interference to each other. If the P/Cs for different MMNs from the same manufacturer are able to communicate with each other, they can coordinate their networks' respective transmissions to avoid transmitting at the same time in the same frequency bands.

49. While the Commission will allow P/C-to-P/C communications to facilitate sharing of the scarce spectrum resource, it will not permit P/Cs to communicate with non-implanted devices for other purposes. This will prevent the 413–457 MHz spectrum from being used as backhaul to move data from an MMN to devices outside the network. This is the rule currently in place for MedRadio devices under our existing rules and is needed because the 413–457 MHz band remains reserved only for those medical applications that cannot be achieved in other spectrum and allowing other transmissions would cause undesirable spectrum congestion.

50. The Commission also sought comment in the NPRM on whether implant-to-implant communications should be allowed, whether each programmer/controller must always control the transmitters implanted in a single patient, and whether all implants in a patient must be controlled by a single programmer/controller.

51. The Commission will not permit implant-to-implant communications. In making the decision to allow MMNs to use spectrum in the 413–457 MHz band, it has been favorably impressed by the interference mitigation techniques that AMF has demonstrated in the independent test described in the Aerospace Report. The system tested relied on a P/C external to the body to schedule the implant transmissions in accordance with these mitigation techniques. The Commission has no evidence on the record that MMNs can successfully mitigate the effects of interference if implants are permitted to communicate with each other outside the control of a P/C. As a result, the Commission cannot reach the conclusion that such a network would be able to function in these bands with the incumbent services.

52. The Commission will allow multiple MMNs to exist within a single patient with each network having its own separate P/C. The configuration of the networks for a particular patient should be determined by the medical needs of the patient and the limits of existing technology. This may require the use of different networks to accomplish different functions. On the other hand, the Commission will not permit a P/C to control implanted devices in multiple patients. Given the power limits of the MMN devices, it

expects that the P/C will have to be within a few meters of the patient at all times. Allowing a single P/C to control implants in more than one patient would require the patients to remain in close proximity at all times, which does not appear to be practical. No commenter has suggested a scenario for which such an accommodation would be useful.

53. *Emission Bandwidth.* In the NPRM, the Commission sought comment on the maximum emission bandwidth that should be allowed for MMN devices. Each of the four segments of the 413–457 MHz band allocated in this proceeding for use by MMN devices occupies six megahertz of spectrum. Alternatively, it also sought comments on whether a smaller maximum emission bandwidth (*e.g.,* three megahertz) might be sufficient for MMN purposes and might further improve spectrum use and efficiency.

54. The Commission adopted a maximum emission bandwidth of six megahertz. It sees no reason to limit the emission bandwidth to three or five megahertz considering that we are allocating six megahertz bands for use by MMNs. This will provide flexibility for future, more efficient system design. The Commission notes that the maximum emission bandwidth of the MMN signals will also be constrained by the unwanted emission limits that it is adopting.

55. *Channelization.* In the NPRM, the Commission suggested that one approach to channelization would be to adopt rules that do not specify any particular channeling plan, thereby following the approach used with the existing MedRadio Service. The Commission sought comment on whether it should require a specific channel plan.

56. No parties suggested a channelization plan other than AMF's proposal for centering the signals in each of the four bands. Given that no parties suggest a channelization plan, the Commission has no grounds for adopting one, nor does it see any reason to specify that emissions be based around a center frequency in each of the four bands as AMF has proposed. Because MMN manufacturers will have to design equipment to operate on specific frequencies, the Commission recognizes that there would be little or no added equipment design cost if it were to specify a particular channel plan or center frequency. Nevertheless, the Commission sees no benefit in doing so, as it would limit the flexibility available for future system design. Accordingly, the Commission will not adopt rules specifying a channelization plan for MMN devices.

57. *Transmitter Power.* In the NPRM, the Commission sought comment on the appropriate transmitted power for MMNs. AMF suggested in its petition that each implantable microstimulator could be limited to a maximum EIRP of 200 microwatts and each P/C transmitter could be limited to a maximum EIRP of 1 milliwatt.

58. The Commission shall adopt the transmitter power limits in AMF's proposed rules with one minor change to reflect the fact that it is allowing MMNs to use a six megahertz maximum emission bandwidth instead of a five megahertz emission bandwidth as AMF proposed. The Commission will limit the maximum EIRP of any MMN transmitter to the lesser of 1 mW or (10 log B − 7.782) dBm where B is the 20 dB emission bandwidth of the transmitted signal in MHz. The Commission believes that these devices transmitting at these power limits will not cause interference to other services in the 413–457 MHz band. The rules it adopted will apply the same transmitter power limits to both implanted transmitters and the P/C transmitter. The Commission sees no reason to apply a stricter power limit to implanted transmitters considering that the signals from these devices will be attenuated by body tissue. For this reason an implanted transmitter is even less likely to cause interference than a P/C transmitter operating at the same power level. The Commission will also not place a limit on the number of devices in an MMN network or aggregate the powers of the devices. No one has suggested a limit on the number of devices or how the power of multiple devices may be aggregated. The Commission notes that because the implant devices in an MMN will only transmit under the control of the P/C, as a practical matter only one implant device in an MMN would transmit at any one time. Consequently, it sees no need to aggregate the powers of the multiple devices in the MMN for purposes of establishing a transmitter power limit.

59. *Duty Cycle.* In the NPRM, the Commission sought comment on the appropriate duty cycle requirements for MMNs. In its petition AMF stated that ''each implanted microstimulator transmits data for approximately *5* microseconds every 11 milliseconds and receives data for approximately 6 microseconds every 11 milliseconds (*i.e.,* less than 0.05 percent transmit duty cycle). For a system with 10 to 20 implanted microstimulators, the transmit duty cycle of the MCU is approximately 3 percent.'' AMF made a similar statement in its comments filed subsequent to the NPRM when describing the operation of its prototype MMNs, but it did not include a duty cycle specification in the rules it concurrently proposed. In a recent *ex parte* submission, AMF indicated that it had reached agreement with the United States Department of Defense that a 3 percent maximum duty cycle for P/Cs would be appropriate.

60. The Commission finds that it is important to specify a maximum duty cycle for MMNs. Because each P/C will occupy a frequency band for a fraction of the time, other MMNs will be able to make use of the frequency band during the remainder of the time, thus facilitating sharing among multiple MMNs. Specifying a maximum duty cycle will also help the MMNs share the frequency bands with pulse radars with short duration signals that are present in the 426–432 MHz and 438–444 MHz bands. Based on the JSC Report and Aerospace Report, the Commission concluded that the record demonstrates that MMNs can operate on a compatible secondary basis with primary Federal systems in these bands. The JSC Report assumed a P/C duty cycle of 3 percent in conducting the analysis that concluded that MMNs would be operationally compatible and not cause interference to Federal systems. Because the Commission has no information on how the conclusions of the JSC Report would be affected if the P/C duty cycle were allowed to rise above 3 percent, and in recognition of the concurrence of AMF and the Department of Defense that a 3 percent maximum duty cycle is appropriate for MMNs, it adopted rules that specify a maximum duty cycle of 3 percent for P/Cs.

61. *Unwanted Emissions.* The existing MedRadio rules under part 95 set limits on unwanted emissions from medical transmitting devices operating in the 401–406 MHz band. As delineated therein, these provisions include limits on both in-band and out-of-band radiation. AMF has proposed emissions limits that are similar to the existing MedRadio rules. No parties commented on the unwanted emissions limits. The rule the Commission adopted applies these emissions limits to these frequency bands. Under this approach, in the first 2.5 megahertz beyond any of the frequency bands authorized for MMN operation, the EIRP level associated with any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 megahertz of the fundamental emission. In addition, emissions more than 2.5

megahertz outside of the authorized bandwidth must meet the frequency-dependent set of electric field strength limits of new § 95.635(d)(1)(iv) of the rules as set forth in Appendix A of the R&O.

62. *Frequency Stability.* In the NPRM, the Commission sought comment on whether each MMN transmitter should be required to maintain a frequency stability as specified in the current MedRadio rules of +/−100 ppm of the operating frequency over the range: (1) 25 °C to 45 °C in the case of MMN implant transmitters; and (2) 0 °C to 55 °C in the case of MMN programmer/control transmitters. AMF suggested extending this existing frequency stability criterion in its rulemaking petition. Sienkiewicz argues that a frequency stability requirement is unnecessary if there is no channelization scheme and that devices from different manufacturers do not need to talk to each other (*i.e.,* if there is no common contention protocol). Even if a frequency stability criterion is needed, he thinks that the criterion can be ten times more relaxed than the suggested standard, but he acknowledges that the +/−100 ppm standard is common in off-the-shelf oscillators.

63. The +/−100 ppm frequency stability criterion is the standard for MedRadio devices in the current rules and represents good engineering practice. As Sienkiewicz acknowledges, oscillators that meet this standard are readily available. AMF, which has built functioning equipment, believes it is an appropriate standard. The Commission agrees and sees no reason to depart from the current MedRadio frequency stability criterion. The Commission will apply this standard to MMN devices.

64. *Antenna Locations.* In the NRPM, the Commission sought comment on applying the existing MedRadio requirement that no antenna for a control transmitter be configured for permanent outdoor use. No one objected to this proposal, and the Commission will retain this rule for MMNs. Additionally, ARRL stated that only portable, body-worn MMN devices should be permitted and that no fixed antenna is appropriate in this frequency range. The rules adopted by the Commission will only permit MMNs that contain implanted devices and a programmer/controller transmitter to operate in the MedRadio Service in these frequency bands and the limited transmit power permitted under our rules will limit the programmer/controller to locations on or in close proximity to the patient. Because the rules will effectively restrict MMNs to portable body-worn devices and preclude the use of fixed antennas, the Commission concluded that it is unnecessary for us to adopt a new rule containing these restrictions.

65. *RF Safety.* In the NPRM, the Commission noted that portable devices are subject to § 2.1093 of its rules, pursuant to which an environmental assessment must be prepared under § 1.1307, and that these rule sections also govern existing MedRadio devices. The Commission further noted that its ongoing RF safety proceeding (ET Docket No. 03–137) anticipated dealing with proposed changes in the Commission's rules regarding human exposure to RF electromagnetic fields in a more comprehensive fashion. The NPRM only sought comment on whether MMN implant and programmer/controller transmitters should be deemed portable devices subject to §§ 2.1093 and 1.1307 of the existing rules. No commenters addressed this issue. Because existing MedRadio devices are considered portable devices and the Commission has no reason to treat MMN devices differently, it shall deem MMN devices to be portable devices subject to §§ 2.1093 and 1.1307 of its rules.

66. The ARRL stated that ''no rules should be enacted without a comprehensive series of field tests that assure patient safety in the presence of typical RF fields in the bands at issue in this proceeding.'' To the extent that these comments relate to RF safety matters, they are misplaced. Given the ongoing Commission proceeding on RF safety in ET Docket 03–137, the NPRM did not request duplicative comment in this proceeding. Rather, the only question we raised in the NPRM that implicated RF safety concerns was the categorization issue, *i.e.,* whether MMN devices should be subject to the RF exposure limits applicable to portable devices, as are other MedRadio devices, or the limits applicable to mobile devices. Consequently, because matters concerning RF safety are more appropriately addressed in ET Docket 03–137 and not here ARRL should raise any specific concerns it has regarding RF safety directly in ET Docket 03–137.

67. *Miscellaneous Provisions.* In the NPRM, the Commission sought comment on a number of provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements, and marketing limitations that mirror the existing MedRadio rules.

68. As the Commission proposed in the NPRM, it will require each MMN transmitter authorized to operate in the 413–457 MHz band to be certificated. This requirement will not apply to transmitters that are not marketed for use in the United States, are being used in the United States by individuals who have traveled to the United States from abroad, and comply with the applicable technical requirements. The Commission also adopted the proposals in the NPRM that MedRadio devices in the 413–457 MHz band be authorized to operate anywhere CB station operation is authorized under § 95.405 and not be required to transmit a station identification announcement. In addition, it will apply the existing MedRadio rule that requires that all non-implanted MMN transmitters be made available for inspection upon request by an authorized FCC representative. Under this provision, persons operating implanted MMN transmitters are required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference. These requirements are all the same as the existing MedRadio rules for the 401–406 MHz band.

69. In the NPRM, the Commission sought comment on whether to require the manufacturers of MMN transmitters to include with each transmitting device the following disclosure statement:

> This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands, 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 MedRadio 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.

The Commission also sought comment on requiring that MMN programmer/control transmitters be labeled and bears the following statement in a conspicuous location on the device:

> This device may not interfere with stations authorized to operate on a primary basis in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands, and must accept any interference received, including interference that may cause undesired operation.

The Commission did not propose an analogous labeling requirement for implant transmitters but instead sought comment on whether to require that the implant transmitters be identified with a serial number.

70. The Commission does not believe that the proposed labeling will be ''useless'' once the implanted MMN devices are placed within the body as claimed by SBE because only the P/C transmitter will bear a label, and it will not be implanted in the body. The proposed disclosure and labeling statements are based on the requirements for the MedRadio Services (and the MICS before that) that have been in place since 1999. These notices have served us well since that time, and it sees no reason to change them now. The Commission notes that MMN devices are medical devices which will be used only under the direction of knowledgeable medical personnel. As such, the notices are not aimed at consumers but instead at medical professionals who are in the best position to give appropriate patient advice. The Commission therefore believes that the notice and labeling requirements are sufficient and adopted them as proposed. These disclosure and labeling requirements provide an important benefit to medical professionals by warning of the secondary status of the MMN devices. These requirements are consistent with those that are in place for similar medical devices that are authorized under the Commission's rules, and so the costs should be similar. Therefore, the Commission sees no reason why disclosure and labeling requirements should be more burdensome in the case of MMNs.

71. No one commented on the proposal that implant transmitters be identified with a serial number. This is the same requirement that MedRadio devices must meet under our existing rules. The Commission therefore adopts this requirement. Doing so will make it easier to identify particular MMN implant devices, and this information is limited enough to be placed on tiny devices. As proposed, the Commission will allow the FCC ID number associated with the transmitter and the information required by § 2.925 of the FCC rules to be placed in the instruction manual for the transmitter in lieu of being placed directly on the transmitter.

72. In the NPRM the Commission also proposed to provide that MMN transmitters intended for operation in any portions of the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands may be marketed and sold only for those permissible uses described above. No one objected to this proposal, which currently is part of the existing MedRadio rules. Given our expressed intent to limit use of these frequency bands to MedRadio applications that cannot be achieved in other spectrum, the Commission believes that this requirement is necessary, and therefore adopts it.

Final Regulatory Flexibility Analysis

73. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Notice of Proposed Rulemaking (NPRM).[2] The Commission sought written public comment on the proposals in the NPRM, including comment on the IRFA. No comments were received addressing the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.[3]

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

74. The Report and Order (R&O) expands the Medical Device Radiocommunication (MedRadio) Service under part 95 of the Commission's rules to enable the operation of medical micro-power networks (MMNs) consisting of implantable medical devices and associated external programmer/controllers (P/C). These MMNs will employ functional electric stimulation (or FES) techniques to serve as an artificial nervous system to restore sensation, mobility, and function to paralyzed limbs and organs. The R&O establishes a secondary allocation in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands for MedRadio with use limited to MMNs.

75. The *R&O* adopts technical and service rules to govern the operation of MMNs in these four frequency bands. Because MMNs will operate on a secondary basis, they must accept interference from and not cause interference to primary services operating in these frequency bands. Consequently, these rules must prevent MMNs from causing interference to the other services operating in these bands. Since MMNs will be used for medical purposes, the rules must also provide assurance that they can reliably function in these frequency bands in the presence of signals from primary services operating these bands. For the most part the adopted rules mirror the existing rules that apply to MedRadio in the 401–406 MHz band in part 95 of the Commission's rules with modifications to account for the MMN's wider bandwidth, higher transmission power, and need to operate in the presence of other primary services.

76. The proposed action is authorized under sections 4(i), 301, 302, 303(e), 303(f), 303(r), and 307(e) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f), 303(r), and 307(e).

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

77. There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

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

78. 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 rules and policies adopted herein.[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] Nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA.

79. *Personal Radio Services.* The Medical Device Radio Communications Services are being placed within part 95 of our rules (''Personal Radio Services''). The Commission has not developed a small business size standard specifically applicable to these services. Therefore, for purposes of this analysis, the Commission uses the SBA small business size standard for the category

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

[2] In the Matter of Amendment of parts 2 and 95 of the Commission's Rules to Provide Additional Spectrum for the Medical Device Radiocommunication Service in the 413–457 MHz band, ET Docket No. 09–36, RM–11404, *Notice of Proposed Rulemaking,* 24 FCC Rcd 3445, 3463 (2009).

[3] *See* 5 U.S.C. 604.

[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 the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), 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**.''

[7] 15 U.S.C. 632 (1996).

Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees.[8] Census data for 2007 show that there were 1,383 firms that operated that year.[9] Of those 1,368 had fewer than 100 employees. 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 cover a broad range of uses.[10] 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 definition that might be directly affected by the proposed rules adopted herein.

80. *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.[11] According to Census bureau data for 2007, there were a total of 919 firms in this category that operated for the entire year. Of this total, 771 had fewer than 100 employees and 148 had more than 100 employees.[12] Thus, under this size standard, the majority of firms can be considered small.

81. We do note, however, that the allocation for the twenty-four megahertz of spectrum in four frequency bands for the Medical Device Radio Communications Service would be limited to use by MMNs. To date no entities are producing MMNs on a commercial basis. However, one entity, the Alfred Mann Foundation (AMF), has produced prototype MMN devices. We have no data on the size of AMF in terms of number of employees or revenue, but we presume that AMF is a small entity. In general, there are only a small number of manufacturers who produce wireless implanted medical devices (less than ten), 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 tend to focus very narrowly on this highly specialized niche market.

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

82. The *R&O* adopts no reporting or record keeping requirements. However, the R&O does adopt a number of service and technical rules that apply to all entities who manufacture and use MMN devices in the four frequency bands. Under the adopted rules the MMNs will not require individual licenses but instead will qualify for license-by-rule operation [13] pursuant to section 307(e) of the Communications Act (Act).[14] The rules generally require that MMNs be able to operate in the presence of other primary and secondary users in these frequency bands.[15] MMNs must be capable of operating on any of the four allocated frequency bands.[16] The programmer/controller (P/C) in the MMN will be required to monitor the frequency band in which the MMN is operating at least once a second and must monitor the other frequency bands often enough that when it does switch frequency bands it has monitored the band it is switching to in the two seconds prior to switching.[17] The P/C must be capable of determining when either direction of the communication link between the P/C and the implanted devices is becoming degraded to the extent that communication is likely to be lost for more than 45 milliseconds. When the P/C makes this determination the MMN is required to move to another frequency band. The P/C will also be required to switch to another frequency band if during the monitoring of the occupied frequency band it determines that there is a received signal with power greater than −60 dBm in any 12.5 kHz bandwidth that persists for at least fifty milliseconds.[18] The MMN transmitters must incorporate a programmable means to implement a system shutdown process within 45 milliseconds of a communication failure or on command from the P/C.[19]

83. MMN use shall be restricted for use by persons only for diagnostic and therapeutic purposes and only to the extent that such devices have been provided to a human patient under the direction of a duly authorized health care professional.[20] P/Cs in different MMNs may communicate with each other for the purposes of coordination of the use of the spectrum resource.[21] However, P/Cs may not communicate with non-implanted devices for other purposes.[22] Implanted MMN devices may not communicate directly with other MMN implanted devices. Multiple MMNs may be present within one patient with each MMN having its own P/C.[23] However, a P/C may not control implanted devices in multiple patients.

84. MMNs may transmit in a maximum emission bandwidth of six megahertz. MMN transmitters may transmit with a maximum EIRP of lesser of 1 mW or (10 log B − 7.782) dBm here B is the 20 dB emission bandwidth of the transmitted signal in MHz.[24] The P/C of an MMN may transmit with a maximum duty cycle of 3 percent.[25] The MMN must meet specific limits on both in-band and out-of-band emissions.[26]

85. MMN transmitters will be required to maintain a frequency stability as specified in the current

[8] *See* 13 CFR 121.201, NAICS code 517210.

[9] U.S. Census Bureau, 2007 Economic Census, Sector 51, 2007 NAICS code 517210 (rel. Oct. 20, 2009), *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=700&-ds_name=EC0751SSSZ5&-_vlang=en.*

[10] 47 CFR part 90.

[11] 13 CFR 121.201 NAICS code 334220.

[12] *See http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=4500&-ds_name=EC0731SG3&-_lang=en.*

[13] *See* 47 CFR 95.1201.

[14] Under section 307(e) of the Act, the Commission may authorize the operation of radio stations by rule without individual licenses in certain specified radio services when the Commission determines that such authorization serves the public interest, convenience, and necessity. The services set forth in this provision for which the Commission may authorize operation by rule include: (1) The Citizens Band Radio Service; (2) the Radio Control Service; (3) the Aviation Radio Service; and (4) the Maritime Radio Service. *See* 47 U.S.C. 307(e)(1).

[15] *See* paragraph 56 in this Report and Order.

[16] *See* paragraph 57 in this Report and Order.

[17] *See* paragraph 59 in this Report and Order.

[18] *See* paragraph 60 in this Report and Order..

[19] *See* paragraph 61 in this Report and Order.

[20] *See* paragraph 65 in this Report and Order.

[21] *See* paragraph 67 in this Report and Order.

[22] *See* paragraph 68 in this Report and Order.

[23] *See* paragraph 70 in this Report and Order.

[24] *See* paragraph 79 in this Report and Order.

[25] *See* paragraph 81 in this Report and Order.

[26] *See* paragraph 82 in this Report and Order.

MedRadio rules of +/− 100 ppm of the operating frequency over the range: (1) 25 °C to 45 °C in the case of MMN implant transmitters; and (2) 0 °C to 55 °C in the case of MMN programmer/control transmitters.[27]

86. MMN transmitters must be certificated except for such transmitters that are not marketed for use in the United States, are being used in the United States by individuals who have traveled to the United States from abroad, and comply with the applicable technical requirements.[28] MMNs may be operated anywhere that CB station operation is authorized under § 95.405 and not be required to transmit a station identification announcement.[29] All non-implanted MMN transmitters must be made available for inspection upon request by an authorized FCC representative. Manufacturers of MMN transmitters must include with each transmitting device a disclosure statement and each MMN programmer/controller must be labeled with a statement.[30] MMN transmitters must be labeled with a serial number, but this serial number may be placed in the instruction manual for the transmitter in lieu of being placed directly on the transmitter.[31]

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

87. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such 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 such small entities.'' [32]

88. We are adopting a license-by-rule approach for MMN operations. This should decrease the cost of MMN use for small entities as compared to a licensing approach because they will not be subject to the expense of obtaining a license.

89. The Commission has adopted a requirement that MMNs be capable of operating in any of the four allocated frequency bands. It do not believe this requirement will increase the cost of equipment unreasonably or be burdensome for manufacturers to meet. We note that these four bands are relatively close in frequency and thus only a single transmitter and one antenna are necessary to cover these four bands. We believe that the components to enable manufacturers of MMNs to meet this requirement should be readily available since equipment is currently designed to operate across the Federal mobile bands between 406.1 MHz and 450 MHz and non-Federal mobile bands between 450 MHz and 512 MHz.

90. As described we have adopted requirements that the P/C of an MMN monitor the frequency bands and switch frequency bands under certain circumstances. We considered not imposing any frequency monitoring requirements on MMNs. However, we believe that this requirement is necessary because MMNs will operate in frequency bands where other services will operate on a primary basis. The MMNs must therefore be capable of detecting signals from these other services and taking steps to minimize the effects of these signals on MMN operations or switching frequency bands. Because MMNs will be used for medical purposes, they must be reliable and therefore these frequency monitoring requirements are necessary. We do not believe this monitoring requirement will add significant cost to MMN equipment since radios now operating in these bands also have a requirement to monitor channels prior to transmitting on them.[33]

91. The requirement that MMN transmitters maintain a frequency stability of +/−100 ppm will not impose significant costs on small entities because oscillators that meet this standard are readily available.

92. We have adopted various provisions regarding equipment certification, authorized locations, station identification, station inspection, disclosure policy, labeling requirements and marketing limitations that mirror the existing MedRadio rules. We note that the certification and inspection requirements apply to a broad range of wireless devices within the Commission's jurisdiction and are a necessary part of insuring that the Commission's technical rules are followed. We therefore did not consider alternatives to these requirements. The disclosure and labeling requirements inform interested parties about limitations on use of the MMN devices, such as the fact that they may not cause interference to and must accept interference from other stations operating on a primary basis in these bands. We therefore believe that the disclosure and labeling requirements are useful and that they will not have a significant cost. The marketing limitation permits MMNs to be marketed and sold only for the types of communication that are permitted under the rules the Commission has adopted. We do not believe this will impose significant costs on small entities.

93. *Report to Congress:* The Commission will send a copy of the Report and Order, including this FRFA, in a report to Congress pursuant to the Congressional Review Act.[34] 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

94. Pursuant to the authority contained in Sections 4(i), 301, 302, 303(e), 303(f), 303(r), and 307(e) of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 301, 302, 303(e), 303(f), 303(r), and 307(e), this Report and Order *is adopted* and Parts 2 and 95 of the Commission's Rules *are amended* as set forth in the Appendix February 27, 2012.

List of Subjects in 47 CFR Parts 2 and 95

Communications equipment, Radio.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Final Rules

For the reasons discussed above, the Federal Communications Commission amends title 47 of the Code of Federal Regulations, Parts 2 and 95, as follows:

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

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

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

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

■ a. Pages 26 through 28 are revised.

■ b. In the list of United States (US) Footnotes, footnote US64 is added and footnote US345 is removed.

[27] *See* paragraphs 83–84, in this Report and Order.

[28] *See* paragraph 89 in this Report and Order.

[29] *See* paragraph 89 in this Report and Order.

[30] *See* paragraph 92 in this Report and Order.

[31] *See* paragraph 93 in this Report and Order.

[32] 5 U.S.C. 603(c)(1)–(c)(4).

[33] *See* paragraph 59 in this Report and Order.

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

The revisions and addition read as follows:

§ 2.106 Table of Frequency Allocations.

* * * * *

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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 5.208B 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) US320 US324 SPACE RESEARCH (space-to-Earth) 5.263 Space operation (space-to-Earth) 5.264 US319	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) US64 US384	401-402 METEOROLOGICAL AIDS (radiosonde) US70 SPACE OPERATION (space-to-Earth) Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US64 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) US64 US384	402-403 METEOROLOGICAL AIDS (radiosonde) US70 Earth exploration-satellite (Earth-to-space) Meteorological-satellite (Earth-to-space) US64 US384	
403-406 METEOROLOGICAL AIDS Fixed Mobile except aeronautical mobile	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US64 G6	403-406 METEOROLOGICAL AIDS (radiosonde) US70 US64	
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 (EPIRBs) (80V) Aviation (ELTs) (87F) Personal Radio (95)
406.1-410 FIXED MOBILE except aeronautical mobile RADIO ASTRONOMY 5.149	406.1-410 FIXED MOBILE RADIO ASTRONOMY US74 US13 US117 G5 G6	406.1-410 RADIO ASTRONOMY US74 US13 US117	Private Land Mobile (90)

Table of Frequency Allocations — 410-698 MHz (UHF) — Page 27

International Table			United States Table		FCC Rule Part(s)
Region 1 Table	Region 2 Table	Region 3 Table	Federal Table	Non-Federal Table	
410-420 FIXED MOBILE except aeronautical mobile SPACE RESEARCH (space-to-space) 5.268			410-420 FIXED MOBILE SPACE RESEARCH (space-to-space) 5.268 US13 US64 G5	410-420 US13 US64	Private Land Mobile (90) MedRadio (95I)
420-430 FIXED MOBILE except aeronautical mobile Radiolocation 5.269 5.270 5.271			420-450 RADIOLOCATION G2 G129	420-450 Amateur US270	Private Land Mobile (90) MedRadio (95I) Amateur Radio (97)
430-432 AMATEUR RADIOLOCATION 5.271 5.272 5.273 5.274 5.275 5.276 5.277	430-432 RADIOLOCATION Amateur 5.271 5.276 5.277 5.278 5.279				
432-438 AMATEUR RADIOLOCATION Earth exploration-satellite (active) 5.279A 5.138 5.271 5.272 5.276 5.277 5.280 5.281 5.282	432-438 RADIOLOCATION Amateur Earth exploration-satellite (active) 5.279A 5.271 5.276 5.277 5.278 5.279 5.281 5.282				
438-440 AMATEUR RADIOLOCATION 5.271 5.273 5.274 5.275 5.276 5.277 5.283	438-440 RADIOLOCATION Amateur 5.271 5.276 5.277 5.278 5.279				
440-450 FIXED MOBILE except aeronautical mobile Radiolocation 5.269 5.270 5.271 5.284 5.285 5.286			5.286 US64 US87 US230 US269 US270 US397 G8	5.282 5.286 US64 US87 US230 US269 US397	
450-455 FIXED MOBILE 5.286AA			450-454 5.286 US64 US87	450-454 LAND MOBILE 5.286 US64 US87 NG112 NG124	Remote Pickup (74D) Low Power Auxiliary (74H) Private Land Mobile (90) MedRadio (95I)
5.209 5.271 5.286 5.286A 5.286B 5.286C 5.286D 5.286E			454-456	454-455 FIXED LAND MOBILE US64 NG12 NG112 NG148	Public Mobile (22) Maritime (80) MedRadio (95I)
455-456 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E	455-456 FIXED MOBILE 5.286AA MOBILE-SATELLITE (Earth-to-space) 5.286A 5.286B 5.286C 5.209	455-456 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E	US64	455-456 LAND MOBILE US64	Remote Pickup (74D) Low Power Auxiliary (74H) MedRadio (95I)

456-459 FIXED MOBILE 5.286AA 5.271 5.287 5.288			456-459 5.287 5.288 US64	456-460 FIXED LAND MOBILE 5.287 5.288 US64 NG12 NG112 NG124 NG148	Public Mobile (22) Maritime (80) Private Land Mobile (90) MedRadio (95I)
459-460 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E	459-460 FIXED MOBILE 5.286AA MOBILE-SATELLITE (Earth-to-space) 5.286A 5.286B 5.286C 5.209	459-460 FIXED MOBILE 5.286AA 5.209 5.271 5.286A 5.286B 5.286C 5.286E	459-460		
460-470 FIXED MOBILE 5.286AA Meteorological-satellite (space-to-Earth)			460-470 Meteorological-satellite (space-to-Earth)	460-462.5375 FIXED LAND MOBILE 5.289 US201 US209 NG124 462.5375-462.7375 LAND MOBILE 5.289 US201 462.7375-467.5375 FIXED LAND MOBILE 5.287 5.289 US73 US201 US209 NG124 467.5375-467.7375 LAND MOBILE 5.287 5.289 US201 467.7375-470 FIXED LAND MOBILE 5.288 5.289 US73 US201 NG124	Private Land Mobile (90) Personal Radio (95) Private Land Mobile (90) Personal Radio (95) Maritime (80) Private Land Mobile (90)
5.287 5.288 5.289 5.290 470-790 BROADCASTING	470-512 BROADCASTING Fixed Mobile 5.292 5.293 512-608 BROADCASTING 5.297 608-614 RADIO ASTRONOMY Mobile-satellite except aeronautical mobile-satellite (Earth-to-space) 614-698 BROADCASTING Fixed Mobile 5.293 5.309 5.311A	470-585 FIXED MOBILE BROADCASTING 5.291 5.298 585-610 FIXED MOBILE BROADCASTING RADIONAVIGATION 5.149 5.305 5.306 5.307 610-890 FIXED MOBILE 5.313A 5.317A BROADCASTING 5.149 5.305 5.306 5.307 5.311A 5.320	5.287 5.288 5.289 US73 US201 US209 470-608 608-614 LAND MOBILE (medical telemetry and medical telecommand) RADIO ASTRONOMY US74 US246 614-698	470-512 FIXED LAND MOBILE BROADCASTING NG5 NG14 NG66 NG115 NG149 512-608 BROADCASTING NG5 NG14 NG115 NG149 614-698 BROADCASTING NG5 NG14 NG115 NG149	Public Mobile (22) Broadcast Radio (TV)(73) LPTV, TV Translator/Booster (74G) Low Power Auxiliary (74H) Private Land Mobile (90) Broadcast Radio (TV)(73) LPTV, TV Translator/Booster (74G) Low Power Auxiliary (74H) Personal Radio (95) Broadcast Radio (TV)(73) LPTV, TV Translator/Booster (74G) Low Power Auxiliary (74H)
5.149 5.291A 5.294 5.296 5.300 5.302 5.304 5.306 5.311A 5.312					

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UNITED STATES (US) FOOTNOTES

* * * * *

US64(a) 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.

(b) The bands 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz are also allocated on a secondary basis to the mobile, except aeronautical mobile, service. The use of this allocation is limited to MedRadio operations. MedRadio stations are authorized by rule and operate in accordance with 47 CFR part 95.

* * * * *

PART 95—PERSONAL RADIO SERVICES

Subpart E—Technical Regulations

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

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

§§ 95.627 and 95.628 [Redesignated as §§ 95.626 and 95.627]

■ 4. Sections 95.627 and 95.628 are redesignated as §§ 95.626, and 95.627, respectively.

■ 5. Newly redesignated § 95.627 is amended by revising the heading and adding introductory text to read as follows:

§ 95.627 MedRadio transmitters in the 401–406 MHz band.

The following provisions apply only to MedRadio transmitters operating in the 401–406 MHz band.

* * * * *

■ 6. New § 95.628 is added to read as follows:

§ 95.628 MedRadio transmitters in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands.

The following provisions apply only to MedRadio transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands as part of a Medical Micropower Network (MMN).

(a) *Operating frequency.* Only MedRadio stations that are part of an MMN may operate in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz frequency bands. Each MedRadio station that is part of an MMN must be capable of operating in each of the following frequency bands: 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz. All MedRadio stations that are part of a single MMN must operate in the same frequency band. A MedRadio station authorized under this part must have out-of-band emissions that are attenuated in accordance with § 95.635.

(b) *Frequency monitoring.* MedRadio programmer/control transmitters must incorporate a mechanism for monitoring the authorized bandwidth of the frequency band that the MedRadio transmitters intend to occupy. The monitoring system antenna shall be the antenna used by the programmer/control transmitter for a communications session.

(1) The MedRadio programmer/control transmitter shall be capable of monitoring any occupied frequency band at least once every second and monitoring alternate frequency bands within two seconds prior to executing a change to an alternate frequency band.

(2) The MedRadio programmer/control transmitter shall move to another frequency band within one second of detecting a persistent (*i.e.,* lasting more than 50 milliseconds in duration) signal level greater than −60 dBm as received by a 0 dBi gain antenna in any 12.5 kHz bandwidth within the authorized bandwidth.

(3) The MedRadio programmer/control transmitter shall be capable of monitoring the authorized bandwidth of the occupied frequency band to determine whether either direction of the communications link is becoming degraded to the extent that communications is likely to be lost for more than 45 milliseconds. Upon making such a determination the MedRadio programmer/control transmitter shall move to another frequency band.

(c) *MedRadio transmitters.* MedRadio transmitters shall incorporate a programmable means to implement a system shutdown process in the event of communication failure, on command from the MedRadio programmer/control transmitter, or when no frequency band is available. The shutdown process shall commence within 45 milliseconds after loss of the communication link or receipt of the shutdown command from the MedRadio programmer/control transmitter.

(d) *MedRadio programmer/control transmitters.* MedRadio programmer/control transmitters shall have the ability to operate in the presence of other primary and secondary users in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands.

(e) *Authorized bandwidth.* The 20 dB authorized bandwidth of the emission from a MedRadio station operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands shall not exceed 6 MHz.

(f) *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.

(g) *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.

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

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

(3) Radiated emissions and EIRP limit measurements may be determined by measuring the radiated field from the equipment under test at 3 meters and calculating the EIRP. The equivalent radiated field strength at 3 meters for 1 milliwatt, 25 microwatts, 250 nanowatts, and 100 nanowatts EIRP is 115.1, 18.2, 1.8, or 1.2 mV/meter, respectively, when measured on an open area test site; or 57.55, 9.1, 0.9, or 0.6 mV/meter, respectively, when measured on a test site equivalent to free space such as a fully anechoic test chamber. Compliance with the maximum transmitter power requirements set forth in § 95.639(f) shall be based on measurements using a peak detector function and measured over an interval of time when transmission is continuous and at its maximum power level. In lieu of using a peak detector function, measurement procedures that have been found to be acceptable to the Commission in accordance with § 2.947 of this chapter may be used to demonstrate compliance. 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).

■ 7. 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. For stations operating in 401.85–402 MHz, the maximum authorized emission bandwidth is 150 kHz. For stations operating in 413–419 MHz, 426–432 MHz, 438–444 MHz, or 451–457 MHz, the maximum authorized emission bandwidth is 6 megahertz.

(2) Lesser emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635. See §§ 95.627(g), § 95.628(h), 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.

* * * * *

■ 8. Section 95.635 is amended by revising paragraph (d) to read as follows:

95.635 Unwanted radiation.

* * * * *

(d) For transmitters designed to operate in the MedRadio service, emissions shall be attenuated in accordance with the following:

(1) Emissions from a MedRadio transmitter shall be attenuated to a level no greater than the field strength limits shown in the following table when they:

(i) Are more than 250 kHz outside of the 402–405 MHz band (for devices designed to operate in the 402–405 MHz band);

(ii) Are more than 100 kHz outside of either the 401–402 MHz or 405–406 MHz bands (for devices designed to operate in the 401–402 MHz or 405–406 MHz bands);

(iii) Are in the 406.000–406.100 MHz band (for devices designed to operate in the 401–402 MHz or 405–406 MHz bands); or

(iv) Are more than 2.5 MHz outside of the 413–419 MHz, 426–432 MHz, 438–444 MHz, or 451–457 MHz bands (for devices designed to operate in the 413–457 MHz band).

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) For devices designed to operate in the 402–405 MHz band: Emissions within the band more than 150 kHz away from the center frequency of the spectrum the transmission is intended to occupy and emissions 250 kHz or less below 402 MHz or above 405 MHz band will be attenuated below the maximum permitted output power by at least 20 dB.

(5) For devices designed to operate in the 401–402 MHz or 405–406 MHz bands: 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) and 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.

(6) For devices designed to operate in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands: In the first 2.5 megahertz beyond any of the frequency bands authorized for MMN operation, the EIRP level associated with any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 megahertz of the fundamental emission.

(7) Compliance with the limits described in subparagraphs (4) through (6) are 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.

* * * * *

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

§ 95.639 Maximum transmitter power.

* * * * *

(f) In the MedRadio Service:

(1) For transmitters operating in the 401–406 MHz band that are not excepted under § 95.627(b) from the frequency monitoring requirements of § 95.627(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 § 95.627(b) from the frequency monitoring requirements of § 95.627(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, 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 the power radiated by any station operating in 401.85–402 MHz shall not exceed 25 microwatts in the 150 kHz bandwidth. See §§ 95.633(e).

(2) For transmitters operating in 413–419 MHz, 426–432 MHz, 438–444 MHz, or 451–457 MHz bands, the peak EIRP over the frequency bands of operation shall not exceed the lesser of 1 mW or 10 log B—7.782 dBm, where B is the 20 dB emission bandwidth in MHz; and the peak power spectral density shall not exceed 800 microwatts per megahertz in any 1 megahertz band.

(3) 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 § 95.627(g) or § 95.628(h), as applicable.

* * * * *

■ 10. Appendix 1 to subpart E of part 95 is amended by adding in alphabetical order the definition ''Medical Micropower Network'' to read as follows:

Appendix 1 to Subpart E of Part 95—Glossary of Terms

* * * * *

Medical Micropower Network (MMN). An ultra-low power wideband network consisting of a MedRadio programmer/control transmitter and medical implant transmitters, all of which transmit or receive non-voice data or related device control commands for the purpose of facilitating functional electric stimulation, a technique using electric currents to activate and monitor nerves and muscles.

* * * * *

Subpart I—Medical Device Radiocommunications Service (MedRadio)

■ 11. Section 95.1209 is amended by revising paragraphs (b), (d), and (e) and by adding paragraphs (f) and (g) to read as follows:

§ 95.1209 Permissible communications.

* * * * *

(b) Except as provided in § 95.627(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.

* * * * *

(d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.627, MedRadio transmitters in the 401–406 MHz band may transmit in accordance with the provisions of § 95.627(a) for no more than 5 seconds without the communications of data; MedRadio transmitters may transmit in accordance with the provisions of § 95.627(b)(2) and (b)(3) for no more than 3.6 seconds in total within a one hour time period; and MedRadio transmitters may transmit in accordance with the provisions of § 95.627(b)(4) for no more than 360 milliseconds in total within a one hour time period.

(e) MedRadio programmer/control transmitters may not be used to relay information in the 401–406 MHz band 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 401–406 MHz band.

(f) MedRadio programmer/control transmitters and medical implant transmitters may not be used to relay information in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands to a receiver that is not part of the same Medical Micropower Network. Wireless retransmission of information to a receiver that is not part of the same Medical Micropower Network must be performed using other radio services that operate in spectrum outside of the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands. Not withstanding the above restrictions, a MedRadio programmer/control transmitter of an MMN may communicate with the MedRadio programmer/control transmitter of another MMN to coordinate transmissions so as to avoid interference between the two MMNs.

(g) MedRadio programmer/control transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands shall not transmit with a duty cycle greater than 3 percent.

■ 12. Section 95.1211 is amended by revising paragraphs (b) and (c) to read as follows:

§ 95.1211 Channel use policy.

* * * * *

(b) To reduce interference and make the most effective use of the authorized facilities, MedRadio transmitters must share the spectrum in accordance with §§ 95.627 or 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, or to other authorized stations operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands. MedRadio stations must accept any interference from stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, and from other authorized stations operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands.

■ 13. Section 95.1215 is revised to read as follows:

§ 95.1215 Disclosure policies.

(a) Manufacturers of MedRadio transmitters operating in the 401–406 MHz band 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.''

(b) Manufacturers of MedRadio transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands must include with each transmitting device the following statement:

''This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands, 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 MedRadio 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.''

■ 14. Section 95.1217 is amended by revising paragraph (a) to read as follows:

§ 95.1217 Labeling requirements.

(a)(1) MedRadio programmer/control transmitters operating in the 401–406 MHz band 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.

(2) MedRadio programmer/control transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands 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 authorized to operate on a primary basis in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands, 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.

* * * * *

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BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 179

[HM–233A]

Special Permit Marking Removal

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Removal of obsolete Special Permit markings.

SUMMARY: On January 25, 2011, FRA published a **Federal Register** document stating that markings on tank cars related to certain gross weight on rail (GRL) Special Permits that had been incorporated into the hazardous materials regulations (HMR) by a Pipeline and Hazardous Materials Safety Administration (PHMSA) rulemaking were required to be removed or obliterated by January 25, 2012, or at each subject tank car's first shopping event, whichever occurred first. This document relieves tank car owners from that previously stated deadline and extends the time for removal of the markings until the date of each subject tank car's next required qualification.

DATES: January 27, 2012.

FOR FURTHER INFORMATION CONTACT: Karl Alexy, Acting Staff Director, Hazardous Materials Division, FRA, 1200 New Jersey Avenue SE., Mailstop 25, Washington, DC 20590, (202) 493–6245.

SUPPLEMENTARY INFORMATION:

I. Background

Historically, the HMR, at 49 CFR 179.13, limited rail tank cars transporting hazardous materials to a GRL limitation of 263,000 pounds. Certain tank cars were able to operate in excess of that GRL limitation if permitted to do so via a Special Permit issued by PHMSA. However, on May 14, 2010, PHMSA published a final rule amending the HMR to incorporate provisions contained in several widely used or longstanding Special Permits that had an established safety record. 75 FR 27205. The final rule amended the HMR to allow, upon the approval of FRA, certain rail tank cars transporting hazardous materials to exceed the GRL limitation of 263,000 pounds without the need for a Special Permit. On January 25, 2011, FRA published a **Federal Register** notice providing such approval for certain tank cars. 76 FR 4250. In that notice, FRA stated that all markings on tank cars subject to the GRL Special Permits that had been incorporated into the HMR by the final rule and approved by FRA were required to be removed or obliterated by January 25, 2012, or at the car's first shopping event, whichever date occurred first.[1]

As background, the requirement to mark Special Permit packagings is provided for in the HMR at 49 CFR 172.302(c). That section requires that a tank car operating under a Special Permit must have the permit number marked on the car (unless this requirement was waived under the terms of a Special Permit). These markings are typically applied to tank cars at the time of their qualification. Certain tank cars exceeding the GRL limitation of 263,000 pounds were previously required to operate under a Special Permit. Those tank cars were required to be marked with the appropriate Special Permit number. However, upon the PHMSA final rule incorporating the applicable GRL Special Permits into the HMR (and FRA's subsequent approval notice) those Special Permits and their corresponding Special Permit number markings on the subject tank cars became obsolete.

Since FRA's publication of the notice, FRA has received a number of requests to extend the deadline for removal of the Special Permit markings on tank cars subject to that notice. Such requests were based on the fact that owners of large fleets of tank cars would have to remove such cars from service in order to send them to an appropriate tank car facility or a loading/unloading facility to have the markings removed. Such a procedure could potentially be both costly to industry and inefficient. The requesters also pointed out that loading/unloading facilities may not be configured to allow for safe access to the location of the existing markings. Finally, personnel at loading/unloading facilities may not have the proper equipment or training to remove or obliterate the appropriate markings.

FRA recognizes the logistical and cost concerns regarding the ability of the railroad industry to comply with the pending January 25, 2012, deadline to remove these now obsolete GRL Special Permit markings. FRA also recognizes that markings are typically applied to tank cars at the time of qualification, and that tank car facilities performing such qualification inspections are equipped to safely access all areas of the tank car and properly remove and/or apply required markings. Also, the obsolete GRL Special Permit markings remaining on the tank cars subject to the FRA notice do not represent a safety or environmental risk. There is no risk as these cars were previously permitted to operate at a GRL of greater than 263,000 pounds via Special Permit, and the now obsolete markings merely reflected such. The PHMSA final rule incorporated the applicable Special Permits into the HMR, which alleviated the need for a Special Permit.

Based on the above discussion, the absence of any safety risk, and in order to avoid annual requests for the extension of the deadline listed in FRA's January 25, 2011, **Federal Register** notice, FRA has decided to extend the deadline for the removal of the obsolete Special Permit markings to the date of each subject tank car's next required qualification pursuant to 49 CFR Part 180.

II. Extension of Deadline To Remove Obsolete PHMSA Special Permit Markings From Tank Cars

Each rail tank car subject to FRA's January 25, 2011, **Federal Register** notice (76 FR 4250) may continue in transportation with the obsolete GRL Special Permit markings present until the date of each car's next required qualification pursuant to 49 CFR Part 180. If a subject tank car continues in transportation after the date of its next required qualification without such marking being removed, FRA reserves the right to take appropriate enforcement action.

Issued in Washington, DC, on January 24, 2012.

Robert C. Lauby,

Acting Associate Administrator for Railroad Safety/Chief Safety Officer.

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[1] The rail tank cars subject to the notice which were required to have such markings removed were cars previously operating under PHMSA Special Permits 11241, 11654,11803, 12423, 12561,12613, 12768, 12903, 13856, 13936, 14004, 14038, 14207, 14398, 14505, and 14734.