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

In the Matter of	)	
	)	
Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules	)	ET Docket No. 10-236
	)	
2006 Biennial Review of Telecommunications Regulations – Part 2 Administered by the Office of Engineering and Technology (OET)	)	ET Docket No. 06-155

MEMORANDUM OPINION AND ORDER AND
FURTHER NOTICE OF PROPOSED RULEMAKING

Adopted: July 6, 2015 **Released: July 8, 2015**

Comment Date: [30 days after date of publication in the Federal Register]
Reply Comment Date: [45 days after date of publication in the Federal Register]

By the Commission:

I. INTRODUCTION

1. In the *Report and Order (R&O)* in this proceeding,[1] the Commission updated its Part 5 Experimental Radio Service (ERS) rules to add options that provide additional flexibility to keep pace with the speed of modern technological change, and an environment where creativity can thrive. Specifically, the Commission added three new types of ERS licenses to supplement the existing conventional ERS license: the program license, the medical testing license, and the compliance testing license.[2] The Commission also modified its market trial rules to eliminate confusion and more clearly articulated its policies with respect to marketing products prior to equipment certification, including establishing a subpart for product development and market trials.[3]

2. In the Memorandum Opinion and Order (MO&O), the Commission, in response to three petitions for reconsideration,[4] modifies certain rules adopted in the *R&O*. Specifically, in response to

[1] See Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules, ET Docket No. 10-236; 2006 Biennial Review of Telecommunications Regulations – Part 2 Administered by the Office of Engineering and Technology (OET), ET Docket No. 06-155; Report and Order, 28 FCC Rcd 758 (2013); Erratum, 28 FCC Rcd 3096 (2013). See also Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules, ET Docket No. 10-236; 2006 Biennial Review of Telecommunications Regulations – Part 2 Administered by the Office of Engineering and Technology (OET), ET Docket No. 06-155; Order on Reconsideration, 28 FCC Rcd 8501 (2013).

[2] *See R&O,* 28 FCC Rcd at 759, para. 1.

[3] Id. at 759, paras. 1-2.

[4] See Petition for Reconsideration of Marcus Spectrum Solutions LLC (Marcus), ET Docket No. 10-236 and ET Docket No. 06-155, filed May 22, 2013; Petition for Reconsideration of Medtronic, Inc. (Medtronic), ET Docket (continued….)

those petitions, we: (1) modify our rules, consistent with past practice, to permit conventional ERS licensees and compliance testing licensees to use bands exclusively allocated to the passive services[5] in some circumstances; (2) clarify that some cost recovery is permitted for the testing and operation of experimental medical devices in clinical medical trials that take place under our market trial rules; and (3) add a definition of "emergency notification providers" to our rules to clarify that all participants in the Emergency Alert System (EAS) are such providers. However, we decline to expand the eligibility for medical testing licenses.

3. In the Further Notice of Proposed Rulemaking (Further Notice), we propose to modify the rules for program licenses to permit experimentation for RF-based medical devices, if the device being tested is designed to comply with all applicable service rules in Part 18 (Industrial, Scientific, and Medical Equipment), Part 95 (Personal Radio Services), Subpart H (Wireless Medical Telemetry Service), or Part 95, Subpart I (Medical Device Radiocommunication Service).

II. MEMORANDUM OPINION AND ORDER

A. Marcus Petition

4. In its petition, Marcus asks that we reconsider a modified provision in Section 5.85(a) of the Commission's Rules that prohibits all experimental licensees from using bands exclusively allocated to the passive services. Marcus notes that, while the modified rule was proposed in the rules appendix of the *Notice of Proposed Rulemaking* (*NPRM*) in this proceeding[6] and adopted in the rules appendix of the *R&O*, it is inconsistent with both the text of the *R&O* and existing policy under which conventional experimental licensees have been allowed to operate in bands allocated to the passive services. Marcus argues that there are legitimate reasons for short-term conventional experiments in some of the bands allocated for passive use. Specifically, Marcus argues that testing new concepts in modulation, high bandwidth, or other technical details in a given non-passive band that might be appropriate as a future home for a new service can be very expensive if that testing requires custom-made equipment. Accordingly, in cases of this nature, Marcus maintains that there is a valid reason to verify the new technical concepts in a band in which equipment is much less expensive, even though long-term use of that band might not be possible.[7] Therefore, Marcus recommends new language for Section 5.85(a) that would prohibit experimental use of the passive bands by the new types of ERS licensees and in product development and market trials, while also specifying that any conventional experimental licensee

(Continued from previous page)
No. 10-236 and ET Docket No. 06-155, filed May 29, 2013; and Petition for Clarification or Reconsideration of Sirius XM Radio Inc. (Sirius XM) and EchoStar Technologies Inc. (EchoStar), ET Docket No. 10-236 and ET Docket No. 06-155, filed May 29, 2013. In July 2013, the Boeing Company (Boeing) and Battelle Memorial Institute (Battelle) filed comments supporting the Marcus Petition. See Comments of the Boeing Company, ET Docket No. 10-236 and ET Docket No. 06-155, filed July 16, 2013; and Reply Comments of Battelle Memorial Institute, ET Docket No. 10-236 and ET Docket No. 06-155, filed July 26, 2013.

[5] Passive services are non-transmitting, receive-only radio services. Examples include the radio astronomy service and some Earth exploration-satellite and space research services.

[6] *See* Promoting Expanded Opportunities for Radio Experimentation and Market Trials Under Part 5 of the Commission's Rules and Streamlining Other Related Rules, ET Docket No. 10-236; 2006 Biennial Review of Telecommunications Regulations – Part 2, Administered by the Office of Engineering and Technology (OET), ET Docket 06-155; *Notice of Proposed Rulemaking,* 25 FCC Rcd 16544 (2010); *Erratum*, 26 FCC Rcd 3828 (2011).

[7] See Marcus Petition at 3-9. Marcus concedes that testing in passive spectrum bands can create concern that some experimenters may attempt to "squat" in such spectrum, but contends that the Commission can require that any experimental applicant who seeks use of a passive band acknowledge that s/he is aware of the passive allocation and has a plan to move the experiment to a non-passive band as the experiment progresses. Id.

proposing use of the passive bands for an experiment must include a justification of why non-passive bands are inadequate for that experiment.[8]

5. Boeing and Battelle support grant of the Marcus Petition, and no commenting party objects. Boeing claims that experimental operations may benefit from or require transmissions in passive bands for such purposes as compliance testing, testing of aircraft and missile systems, and testing of ultra-high bandwidth technology. Boeing also cites a record of conventional experimental license grants in passive bands with no evidence of interference to passive services.[9] Battelle contends that, for some cutting edge technologies, it may be difficult to find a practical testing locale outside the passive bands. Battelle further contends that experimental use of passive spectrum is generally sought only in very limited circumstances, and that there is no documented evidence that use of experimental devices in passive bands has ever caused a problem to passive services. Finally, Battelle contends that any use of passive spectrum necessarily involves coordination with the National Telecommunications and Information Administration (NTIA), which serves as an effective check against experimental use of that spectrum that might potentially create harmful interference to passive services.[10]

6. As Marcus observes, Section 5.85(a) of the rules appendix in the *R&O* is inconsistent with both our existing treatment of conventional ERS licenses and the text of the *R&O*. This inconsistency arose in the *NPRM*, where the text proposed that only program licenses[11] would be prohibited from using "restricted" bands (including passive service bands) listed in Section 15.205(a) of the Commission's Rules.[12] In contrast, Section 5.85(a) of the rules appendix proposed that all experimental use of "any frequency or frequency band exclusively allocated to the passive services" be prohibited.[13] This inconsistency was not addressed by any commenting party, but the Commission's stated intent in the text of the *R&O* was to continue previous practice regarding conventional ERS licenses.[14] In addition, we observe that the Commission stated in the *R&O*: "Due to the nature of the compliance testing process, we will not impose on them most of the limitations and reporting requirements that we are imposing on program licenses. Specifically, because compliance testing often involves emission measurements in restricted bands, compliance testing licensees will be exempt from the prohibition on operating in the restricted bands listed in 15.205(a) of the rules and from operating in the bands allocated exclusively to the passive services."[15] Thus, we modify Section 5.85(a) to permit conventional and compliance testing licensees to operate on passive bands.

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[8] *Id*. at 14.

[9] See Boeing Comments at 3-6.

[10] See Battelle Reply Comments at 4-5.

[11] We note that the *NPRM* proposed to create three types of program licenses – research, innovation zone, and medical; s*ee NPRM,* 25 FCC Rcd at 16548-49, para. 12. Ultimately, however, the Commission created only one type of program license (research), with innovation zones being available to program licensees under certain circumstances and medical testing licenses established as a separate classification. *See R&O*, 28 FCC Rcd at 759, paras. 1-2.

[12] *See NPRM,* 25 FCC Rcd at 16551-52, para. 21.

[13] *Id*. at 16597.

[14] Paragraph 50 of the *R&O* recapped the proposal set forth in the text of the *NPRM* by stating that the *NPRM* "proposed that program licensees – unlike conventional experimental licensees – would not be permitted to operate in the restricted band frequencies;" *see R&O*, 28 FCC Rcd at 776. Further, paragraph 56 of the *R&O* stated that experimenters desiring to use those frequencies "may still do so, but they must apply for a conventional experimental license and be subject to the case-by-case review inherent in that process;" *see R&O*, 28 FCC Rcd at 779.

[15] *See R&O*, 28 FCC Rcd at 795, para. 101.

7. In making these modifications to Section 5.85(a), we observe that a number of conventional experiments have operated in passive service bands without causing harmful interference to passive services, and we concur with Marcus, Boeing, and Battelle that such conventional experimental use should be permitted to continue under some circumstances. We observe that in those instances in which an experimental applicant had requested use of a passive band, OET staff in coordination with NTIA undertook a case-by-case review of the application and imposed specific conditions on the applicant, as warranted, to minimize the potential that the experiment would cause harmful interference to passive service(s) that use that band. We therefore find generally appropriate Marcus's recommended new language for Section 5.85(a) that would continue to permit conventional ERS use of the passive bands under limited circumstances, and further modify the language to also permit compliance testing licensees to use those bands.

B. Medtronic Petition

8. A medical testing experimental radio license (medical testing license) is issued to hospitals and health care institutions that demonstrate expertise in testing and operation of experimental medical devices that use wireless telecommunications technology or communications functions in clinical trials[16] for diagnosis, treatment, or patient monitoring.[17] These licenses are for testing medical devices that would operate under existing rules and use radio frequency (RF) wireless technology for diagnosis, treatment, or patient monitoring for the purposes of, but not limited to, assessing patient compatibility and usage issues, as well as operational, interference, and RF immunity issues.[18] Unlike a conventional experimental license, a medical testing license would allow a health care institution to conduct a wide variety of unrelated clinical trials under a single authorization. The Commission will grant authorizations for a geographic area that is inclusive of an institution's real-property facilities where the experimentation will be conducted and that is under the applicant's control. Applications also may specify, and the Commission will grant authorizations for, defined geographic areas beyond the institution's real-property facilities that will be included in clinical trials and monitored by the licensee.[19]

9. In its petition, Medtronic raises two issues, which we address in turn. First, Medtronic asks that we expand the eligibility for the medical testing license. The second issue pertains to cost reimbursement for clinical trials, which is permitted under Food and Drug Administration (FDA) rules. Medtronic requests that we clarify that such reimbursement does not constitute impermissible marketing under Sections 2.803 or 2.805 of our rules. Medtronic asserts that these changes could greatly facilitate clinical trials because the devices would not need to have first been approved by the Commission under its equipment authorization program.[20] No party filed comments regarding any of the issues raised by Medtronic's petition.

10. ***Medical testing license eligibility.*** Medtronic observes that the *R&O* established this license to meet the needs of the medical community and to allow medical researchers to conduct clinical

[16] The *R&O* stated: "Clinical trials are generally considered to be research studies with human beings that follow a pre-defined protocol. Clinical trials using RF devices may be used, for example, to test a patient's acceptance of a device, to ensure that the device properly provides the necessary treatment, therapy or monitoring, or to determine RF interoperability in a health care of other anticipated use environment." *See R&O*, 28 FCC Rcd at 798, para. 112, fn. 196.

[17] 47 C.F.R. § 5.54(d). Eligible hospitals and health care institutions are those defined in 47 C.F.R. § 95.1103(b).

[18] 47 C.F.R. § 5.402. Medical testing under this license is limited to testing equipment designed to comply with the rules in Part 15, Radio Frequency Devices; Part 18, Industrial, Scientific, and Medical Equipment; and Part 95, Subpart H-Wireless Medical Telemetry Service or Subpart I-Medical Device Radiocommunication Services. *Id.*

[19] 47 C.F.R. § 5.404.

[20] *See* Medtronic Ex Parte Comments, filed July 11, 2014.

trials, but limited eligibility for medical testing licenses to health care facilities.[21] Medtronic notes that FDA rules permit a wide range of entities, including non-health care facilities, to sponsor or conduct clinical trial testing.[22] In particular, Medtronic notes that the FDA classifies certain entities involved in medical device research as either "sponsors" or "sponsor-investigators" of clinical trials, with those terms defined as follows:

> *Sponsor* - A person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.[23]
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> *Sponsor-investigator* - An individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.[24]

11. Medtronic observes that under these FDA classifications, a wide-range of entities, including device manufacturers, act as sponsors[25] and sponsor-investigators of clinical trials and engage in real-world patient testing, but that these entities do not always meet the more limited definition of a "health care facility" under the Commission's rules. Thus, Medtronic argues, a "significant portion" of these entities are not eligible to apply for a medical testing license.[26] These entities, it claims, will be subject to testing limitations and added costs and burdens by having to design their tests to comply with our other experimental authorization rules (or not be able to conduct them in a manner that provides the most utility for device evaluation purposes). Medtronic asserts that our licensing structure is inconsistent with FDA regulations that permit a wider variety of entities to sponsor or conduct clinical trial testing, and creates regulatory uncertainty, does not meet the development and testing needs of the medical community, and threatens to frustrate the very innovation that this proceeding is intended to promote. Medtronic also asserts that the new program experimental license (program license) is inappropriate for medical testing because that license does not unreservedly cover clinical trials. Medtronic therefore

[21] 28 FCC Red at 798-99, paras. 111-12.

[22] The FDA rules refer to clinical investigations which are defined as investigation or research involving one or more subjects to determine the safety or effectiveness of a medical device. *See* 21 C.F.R. § 812.3(h).

[23] 21 C.F.R. § 812.3(n).

[24] *See* 21 C.F.R. § 812.3(o).

[25] We note that a sponsor means a "person," and the FDA broadly defines a person to include "any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit of a Government agency, and any other legal entity." See 21 C.F.R. § 812.3(l). We also note that "sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB [institutional review board] review and approval are obtained, submitting an IDE [investigational device exemption] application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation." See 21 C.F.R. § 812.40. Further, a "sponsor shall ship investigational devices only to qualified investigators participating in the investigation" and "shall select monitors qualified by training and experience to monitor the investigational study in accordance with this part and other applicable FDA regulations." See 21 C.F.R. § 812.43(b) and (d).

[26] See Medtronic Petition at 2.

recommends that the Commission extend the eligibility for medical testing licenses to FDA sponsors and sponsor-investigators of clinical trials involving the testing and operation of new medical devices.[27]

12. In particular, Medtronic argues that expanding the eligibility to device manufacturers would level the playing field under the rules since the line between device manufacturers and health care facilities is blurring as healthcare providers are among those who develop medical devices.[28] More specifically, given this overlap between the two with respect to their involvement in developing such devices, Medtronic argues that the following two disparities in regulatory treatment unfairly skew the playing field: (1) medical testing licensees can operate on frequency bands restricted under Section 15.205(a) if the device being tested complies with rules in Part 18, Part 95, Subpart H (Wireless Medical Telemetry Service), or Part 95, Subpart I (Medical Device Radiocommunication Service), but program and conventional experimental licensees cannot; and (2) medical testing licensees can conduct clinical trials outside the physical facilities under their control, but program licensees cannot.[29]

13. We address separately in the attached Further Notice whether we should permit program licensees to experiment on frequency bands restricted under Section 15.205(a), if the device being tested is designed to comply with all applicable service rules in Part 18 (Industrial, Scientific, and Medical Equipment), Part 95 (Personal Radio Services), Subpart H (Wireless Medical Telemetry Service), or Part 95, Subpart I (Medical Device Radiocommunication Service).[30]

14. After careful consideration, however, we find good reason to deny Medtronic's request. In the *R&O,* the Commission recognized the importance of its experimental licensing program to the development of RF-based medical devices, and its rules provide a variety of authorizations under which medical device experimentation and clinical trials can be conducted, including program licenses, conventional licenses for market trials,[31] and medical testing licenses. The Commission limited the eligibility and scope of a medical testing license to hospitals and health care institutions to address their particular needs in conducting multiple clinical trials, both within their institutions and at defined geographic areas beyond their facilities that will be monitored by the licensee.[32] This license allows a health care institution to assess patient compatibility and use, as well as operational, interference, and RF immunity issues in real use settings.[33] To accomplish this objective, the medical testing license has elements similar to program licenses and to market trial licenses.[34] As with program licenses, a medical testing licensee can conduct multiple unrelated experiments at its own facility that is under its control.[35] As with market trials, the medical testing licensee can request permission to conduct clinical trials at other

[27] Id. at 2-6.

[28] *See* Medtronic Ex Parte Comments, filed June 12, 2014; Medtronic Ex Parte Comments, filed April 16, 2015.

[29] *See* Medtronic Ex Parte Comments, filed April 16, 2015.

[30] The Part 5 rules do not prohibit conventional experimental licensees from experimenting on these frequencies. The scope of a conventional license is determined on a case-by-case basis.

[31] As discussed below, the Commission is modifying Section 5.602 to permit medical testing licensees to follow the market trial rules. See para. 25, infra.

[32] The medical testing license is limited to conducting clinical trials. Health care institutions that want to conduct basic research and experimentation with RF-based medical devices would need to be authorized under either a conventional or program experimental license, as would any manufacturer of RF-based medical devices. *See* R&O, 28 FCC Rcd at 770, para. 33.

[33] *See R&O*, 28 FCC Red at 798-99, para. 112.

[34] *Id.*

[35] *Id*. at 798-800, paras. 111 and 114.

specified locations that it monitors.[36] We envision, for example, that a medical testing license would be helpful to those health care institutions when RF-based medical devices used in clinical trials would be operated primarily within the institution by hospital staff who can observe how those devices perform in the presence of other RF equipment. In the *R&O,* we recognized that, although a health care facility could oversee a clinical trial beyond its facility, it may not want to assume this responsibility in some cases and instead may prefer that the device manufacturer or health practitioner, under a conventional or market trial license, assume responsibility for clinical trials outside the health care facility.[37]

15. We conclude that if we were to expand eligibility for a medical testing licensee to align with the FDA's regulations, we would undermine the Commission's ability to meet its own objectives. Each agency's rules are designed to satisfy different purposes.[38] The Commission's primary concern in authorizing experimentation with RF devices is to ensure that the devices do not cause harmful interference to authorized users of the spectrum and that the devices do not enter into commerce prior to Commission certification. A Part 5 licensee is the party that we hold responsible for the proper operation of the experimental RF devices to avoid harmful interference to authorized spectrum users and to take corrective action as necessary. A Part 5 license also specifies the locations for experimentation, *e.g.*, a conventional license would specify the locations where the licensee is conducting experimentation, and a program license limits operation to locations directly under the licensee's control.[39] The FDA's Investigational Device Exemption (IDE) rules cited by Medtronic are designed for a different purpose – to determine the safety or effectiveness of a medical device. To accomplish this objective, the FDA's regulations allow for different categories of participation in clinical trials (*e.g.,* sponsors who initiate, investigators who conduct trials, and sponsor-investigators who take on both roles). A sponsor does not necessarily conduct the investigation, and thus would not be directly responsible for the operation of the experimental RF-based devices as intended by the Commission's Part 5 rules. Numerous investigators may conduct the clinical trials, often at a variety of locations which are not required to be, and most likely are not, under the sponsor's control. We are concerned that allowing an FDA sponsor or sponsor-investigator to hold a medical testing experimental license would create confusion in determining who is responsible for the proper operation of the experimental RF devices to avoid harmful interference to other spectrum users and to take corrective action as necessary. Also, trials may be conducted by multiple investigators who are not licensees at many different locations that would not be under the licensee's control. This would be contrary to the basic principles underlying the experimental licensing program. We emphasize that any health care facility that wishes to be eligible for grant of a medical testing license must meet all eligibility requirements contained in our rules, including the requisite RF expertise.

16. We find it better serves the public interest to maintain the structure that was adopted by the Commission, wherein a medical testing license is available only to a qualified health care facility that is solely responsible for clinical trials within its institution. The key element here is that the licensee

[36] *See* 47 C.F.R. §5.404. We require that the applicant specify, at the application stage, locations where it intends to conduct trials beyond its own facility over the five year license term. These would be areas close to the licensee's own facility that it closely monitors so that it can effectively manage the interference environment during clinical trials, including satisfying the requirements in rule sections 5.307 ("Responsible Party") and 5.308 ("Stop buzzer") for resolving interference and ceasing operations, as needed. This will permit the licensee, for example, to conduct clinical trials at on-campus residential facilities used by patients participating in clinical trials.

[37] *See* R&O, 28 FCC Rcd at 801-02, para. 117.

[38] The Commission has acknowledged the separate jurisdiction of the FCC and the FDA regarding the use of experimental RF-based devices in clinical trials. *See R&O,* 28 FCC Red at 799, para. 113.

[39] Our program license rules state: "Applications must specify, and the Commission will grant authorizations for, a geographic area that is inclusive of an institution's real-property facilities where the experimentation will be conducted and that is under the applicant's control. If an applicant wants to conduct experiments in more than one defined geographic area, it shall apply for a license for each location." *See R&O,* 28 FCC Red at 849, § 5.304.

controls the facility – and hence the interference environment – where multiple clinical trials are being conducted. The medical testing license is designed to address the particular needs of health care institutions in conducting multiple clinical trials within its institution under real use conditions, whether the RF-based medical devices being tested are manufactured by themselves or other manufacturers. To expand eligibility for this license to any manufacturer of medical devices, we would have to identify the real-property facilities that they control and where clinical trials would be conducted. It seems unlikely that a manufacturer would conduct clinical trials at its manufacturing facility if this does not provide real use conditions. Moreover, as discussed above, Medtronic does not ask to conduct clinical trials at its own facilities but rather to conduct such trials at multiple other locations as approved under FDA rules on a trial-by-trial basis. This is fundamentally different than how the medical testing license is intended to operate.

17. In declining to modify the rules as requested by Medtronic, we note that the Part 5 rules provide other options for conducting clinical trials that other entities, such as sponsors, investigators and medical device manufacturers, can use. First, entities may evaluate product performance of an experimental wireless medical device under a market trial by obtaining a conventional experimental license. Typically, market trials are conducted prior to the production stage to evaluate product performance and customer acceptability under expected use conditions.[40] As with medical testing licenses, market trials are authorized for devices that are designed to comply with existing Commission rules.[41] However, unlike a regular conventional experimental license, a market trial license can be used to conduct clinical trials in locations not under the licensee's direct control, such as at a patient's home. Second, for instances where a party is developing a device that would not be able to be operated in compliance with existing rules, the Commission envisioned that such devices can be tested under a conventional experimental license.[42] In summary, manufacturers of medical devices, whether associated with a health care facility or not, would have similar opportunities for experimenting with such devices even though they may do so under different types of authorizations. Both health care institutions that qualify for a medical testing license and device manufacturers that do not must obtain either a program or conventional experimental license to conduct basic research and experimentation.[43] Device manufacturers that do not qualify for a medical testing license would need to obtain a market trial license to conduct clinical trials, which provides more flexibility than a medical testing license for specifying the area(s) within which the trial will be conducted. Health care facilities that qualify for a medical testing license could conduct clinical trials under either a medical testing license or a market trial license. Under the medical testing license, the licensee is limited to areas close to the licensee's own facility,[44] and if it wants to conduct a clinical trial in a location not specified in its license, it would do so under a market trial license.

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[40] *See* 47 C.F.R. §5.5. *See also* 47 C.F.R. § 5.602 for the rules regarding market trials. The Part 5 rules also permit clinical trials under a conventional license for product development trials, which are defined as: "An experimental program designed to evaluate product performance (including medical devices in clinical trials) in the conceptual, developmental, and design stages, and typically requiring testing under expected use conditions." *See R&O,* 28 FCC Red at 831, § 5.5. Product development trials are usually conducted earlier in the device development process than market trials, and the rules do not permit any type of marketing of the experimental device during a product development trial, thus precluding any reimbursement under FDA rules. S*ee R&O,* 28 FCC Red at 807-08, paras. 135-136; *see also* 47 C.F.R. § 5.601.

[41] *See* 47 C.F.R. §5.602(a). The rule also permit market trials for devices that comply with waivers of rules that are in effect at the time of operation or rules that have been adopted by the Commission, but that have not yet become effective.

[42] See R&O, 28 FCC Red at 807-08, para. 135.

[43] *See* note 32, *supra*.

[44] *See* note 36, *supra*.

18. Also, as acknowledged by Medtronic,[45] the Commission may declare a specific geographic area an innovation zone for the purpose of conducting a clinical trial.[46] Such a declaration, which could be made on our own motion or in response to a public request – such as from a health care facility lacking the RF expertise necessary for obtaining a medical testing licensee – would permit the Commission to designate a defined geographic area and frequency range(s) for specific types of experiments by program licensees within guidelines that we may establish on a case-by-case basis. These innovation zones can include geographic areas beyond a program licensee's authorized area without the licensee having to apply for a new license to cover a new location.[47] Thus, they can serve to effectively extend a program license without the licensee being required to modify its license to cover a new location.[48] Accordingly, innovation zones will provide opportunities for program licensees, including FDA sponsors and sponsor-investigators, to test potentially innovative wireless devices in real world operating environments, such as testing medical devices in health care institutions.[49] In the *R&O*, the Commission stated that this approach "may be particularly useful for manufacturers who want to test medical or other types of equipment that will be used in a health care setting while it is in the product development stage, but who will not be eligible for the medical testing license. A manufacturer of medical devices would be able to continue its product testing for clinical trials under its program license at a designated innovation zone without having to apply for a separate market trial license."[50]

19. As we concluded in the *R&O*, the different licensing options represent a multi-faceted approach to facilitate robust medical RF experimentation that responds to the record developed in this proceeding. The medical testing experimental license complements the types of medical RF experimentation that parties will be able to conduct under a conventional, program, or market trial experimental license. Accordingly, we find that limiting eligibility for a medical testing license to hospitals and health care facilities is not detrimental to medical innovation and product development. Our goal in this proceeding is to facilitate bringing ground-breaking new technologies and services to consumers more rapidly, and we find that our current rules provide the proper incentives toward achieving that goal to both FDA-approved sponsors/sponsor-investigators and to health care facilities. Accordingly, we deny Medtronic's request to expand the eligibility for the medical testing license at this time. As licensees take advantage of the new flexible licenses, we will gain valuable insight as to whether we could modify our rules in the future without sacrificing our objective of ensuring that each clinical trial is conducted in a way that minimizes the potential for harmful interference to authorized services.

20. ***Cost reimbursement for clinical trials.*** The second issue raised by Medtronic pertains to cost reimbursement for clinical trials of experimental medical devices. Medtronic explains that, while manufacturers of medical devices are not permitted by the FDA to profit from clinical trials, they are allowed to recover certain manufacturing, research, development and handling costs associated with FDA-defined "investigational devices." Medtronic further states that the FDA typically allows sponsors to charge investigators for such devices, and that the costs are usually passed on to the clinical trial

[45] See Medtronic Petition at 6-7, n.16.

[46] An innovation zone is a specified geographic location with pre-authorized boundary conditions (such as frequency band, maximum power, etc. Innovation zones will be announced via public notice and posted on the Commission's program experimental registration website. *See R&O,* 28 FCC Rcd at 852, § 5.313.

[47] Id. at 792-93, para. 93. The Commission will grant program licenses for a geographic area that is inclusive of an institution's real-property facilities where the experimentation will be conducted and that is under the applicant's control. If an applicant needs to conduct experiments in more than one defined geographic area, it must apply for a license for each location. Id. at 773-74, para. 45.

[48] *Id*. at 792-93, para. 93.

[49] Id. at 793, para. 94.

[50] Id. at 802, para. 120; 802-03, para. 120, n.212.

subjects.[51] The FDA rules permit a sponsor or investigator to charge subjects for an investigational device, but those entities may not commercialize that device by charging a price larger than that necessary to recover the costs of manufacture, research, development, and handling.[52] Medtronic requests that we clarify that such reimbursement does not constitute impermissible marketing under Sections 2.803 or 2.805 of our rules. Medtronic argues that the requested clarification will ensure consistency between the regulatory regimes of the Commission and the FDA, simplify manufacturers' compliance, and encourage medical device testing and innovation.[53] Medtronic maintains that the purposes of FDA's cost recovery mechanism align with our marketing restrictions, and that permitting cost recovery in clinical trials will encourage medical device research and development that will ultimately benefit consumers.[54]

21. The Commission's rules generally prohibit the operation and marketing of RF products prior to equipment authorization except under certain specified conditions. Section 2.805 ("Operation of radio frequency devices prior to equipment authorization") lists conditions under which RF devices may be operated prior to equipment authorization, including operation under an experimental radio license issued under Part 5 of our rules, and states that an RF device that may be operated prior to equipment authorization "may not be marketed (as defined in § 2.803(a)) except as provided elsewhere in this chapter."[55] Section 2.803 ("Marketing of radio frequency products prior to equipment authorization") defines marketing as "sale or lease, or offering for sale or lease, including advertising for sale or lease, or importation, shipment, or distribution for the purpose of selling or leasing or offering for sale or lease."[56] These restrictions on marketing are intended to prevent the unchecked dissemination of experimental devices into the stream of commerce, where they may not always be easily recalled.[57] We conclude here that accepting reimbursement payments under the FDA's rules for the use of an unauthorized RF device in a clinical trial falls within this definition of "marketing." However, Section 2.803 includes a number of exceptions to the general prohibition against marketing unauthorized equipment. One of those exceptions is for market trials conducted under a Part 5 experimental license.[58] Accordingly, and, as explained below, we clarify that the marketing advocated by Medtronic is permitted on a limited basis under the Section 2.803 exception for market trials conducted by Part 5 experimental licensees.[59]

22. In the *R&O*, the Commission modified its Part 5 rules to provide more flexibility for market trials, including some forms of cost recovery, while continuing to provide safeguards to protect the public. Section 5.602 ("Market Trials") permits marketing of devices (as defined in Section 2.803) and provision of services for hire prior to equipment authorization, provided that the devices included in the market trial are authorized under this rule section and will be operated under the current rules; could

[51] *See* Medtronic Petition at 10-11.

[52] *See* 21 C.F.R. § 812.7(b).

[53] *See* Medtronic Petition at 2.

[54] *Id*. at 9-11.

[55] *See* 47 C.F.R. § 2.805.

[56] *See* 47 C.F.R. §2.803(a).

[57] *See*, *e.g.*, C.T.S. Technology Co., Limited, *Notice of Apparent Liability*, 29 FCC Rcd 8107, 8110 (2014), at para. 10.

[58] 47 C.F.R. § 2.803(c)(1). Other exceptions include limited marketing for certain devices that could be authorized under the current rules, under waivers of such rules that are in effect at the time of marketing, or under rules that have been adopted by the Commission but that have not yet become effective. *See* 47 C.F.R. §2.803(c)(2). Permitted marketing activities include conditional sales contracts, offers for sale, and advertising or displays that notify the prospective buyer that the equipment is subject to FCC rules and approvals. 47 C.F.R. §2.803(c)(2)(i)-(iii).

[59] 47 C.F.R. §2.803(c)(1).

be authorized under waivers of such rules that are in effect at the time of marketing; or could be authorized under rules that have been adopted by the Commission, but that have not yet become effective.[60] The rule stipulates that the experimental licensee must own all transmitting and/or receiving equipment, but also permits the experimental licensee to: (1) sell equipment to other licensees (*e.g.* manufacturer to licensed service provider), and (2) lease equipment to trial participants for purposes of the study.[61] Equipment must be retrieved or rendered inoperable after the trial.[62]

23. We find that, for devices that necessitate an experimental license for the conduct of a clinical trial, the market trial rule allows for some cost recovery for investigational devices used in those trials consistent with the Commission's purpose to prevent the unchecked dissemination of experimental devices into the stream of commerce. While our market trial rules differ from the FDA rules, they do provide manufacturers of experimental medical devices a mechanism for offsetting costs associated with the development of those devices. For example, FDA rules allow sponsors to charge investigators for medical devices and these costs may be passed on to the clinical trial participants, and a Part 5 market trial licensee may sell devices to another licensee (*e.g.*, a health care facility that is a medical testing licensee) or lease medical devices to trial participants, which may permit full or partial cost recovery. We believe that this structure generally accommodates Medtronic's request, and serves the public interest by providing medical device manufacturers an incentive to develop innovative, but potentially costly, devices for use in clinical trials.

24. We also observe that not all clinical trials occur under Part 5 experimental rules. Our experience has been that clinical trials, especially those involving implanted devices which cannot be easily returned to the licensee as our rules require, occur after the FCC has issued an equipment authorization grant for the device. In those cases, there is no FCC marketing restriction that conflicts with FDA rules.

25. We also clarify that a medical testing licensee conducting clinical trials that wants to seek reimbursement under the FDA's rules should follow the requirements for market trials in Section 5.602. In establishing the medical testing license, the Commission observed that the license will allow for "clinical trials of medical devices that have already passed through the early developmental stage and are ready to be assessed for patient compatibility and use, as well as operational, interference, and RF immunity issues in real world situations."[63] This is conceptually analogous to a market trial, which "com[es] later in the development process"[64] and is a "program designed to evaluate product performance and customer acceptability prior to the production stage."[65] Also, both medical testing licenses and market trials licenses are used for devices that will be operated under the current rules; could be authorized under waivers of such rules that are in effect at the time of marketing; or could be authorized under rules that have been adopted by the Commission, but that have not yet become effective. In the *R&O* we stated that we would require a market trial to be authorized under a conventional, rather than a program, license "in recognition of the inherent difference between market trials and 'regular' experimentation and testing – the most prominent difference being the necessity to prevent an experimental licensee from creating a *de facto* service through the experimental licensing process."[66] As

[60] *See* 47 C.F.R. § 5.602(a). Market trials are authorized under a conventional experimental license, *i.e.*, a separate Part 5 license is issued for each trial.

[61] *See* 47 C.F.R. § 5.602(b), (d).

[62] *See* 47 C.F.R. § 5.602(e).

[63] *See R&O,* 28 FCC Rcd at 798, para. 112.

[64] *Id*. at 808, para. 136.

[65] *Id*. at 805-06, para. 128.

[66] *Id*. at 808, para. 137.

we discuss above, clinical trials are analogous to market trials, and should be treated like market trials for cost recovery purposes by the experimental license rules. Accordingly, we modify Section 5.402 to make clear that medical testing licensees may recover their costs to the extent they are permitted by the market trial rule.

26. We also clarify that, under a conventional license issued for a product development trial, a licensee conducting a clinical trial could not be reimbursed for its costs, and we take this opportunity to correct a contradiction in our current rules regarding product development trials. Although Section 2.803 exempts product development trials from the marketing rule for equipment operated prior to certification,[67] the product development trial rule (Section 5.601) expressly prohibits marketing of devices as defined in Section 2.803 or the provision of services for hire.[68] This prohibition in the rule is consistent with the Commission's statement in the *R&O* that licensees conducting a product development trial must not market devices or offer services for hire.[69] The Commission differentiated product development trials, which occur very early in the development process, from market trials for marketing purposes. Market trials, which occur later in the development process, can engage in marketing activity if they use equipment that could be operated under the current rules; could be authorized under waivers of such rules that are in effect at the time of marketing; or could be authorized under rules that have been adopted by the Commission, but that have not yet become effective. Product development trials have no such restrictions and thus restricting marketing is important to prevent the unchecked dissemination of experimental devices into the stream of commerce. Clearly, the Commission's intent was to prohibit marketing for product development trials and erred in its drafting of the marketing exceptions in Section 2.803. Accordingly, we herein correct Section 2.803(c)(1) to refer only to market trials and remove the reference to product development trials. Thus, we note that reimbursement under the FDA's rules for clinical trials would not be permitted for a product development trial.

27. For the reasons discussed above, we conclude that Medtronic's requests are best accommodated under our existing rules. To the extent that cost recovery for medical devices used in clinical trials is done under our market trial rules set forth in Section 5.602, we grant Medtronic's request and clarify that such cost recovery does not constitute impermissible marketing under Sections 2.803 and 2.805 of our rules.

C. Sirius XM and EchoStar Petition

28. In their petition, Sirius XM and EchoStar request that we add a definition of "emergency notifications" to our rules to clarify that all participants in the Emergency Alert System[70] are emergency notification providers, and are therefore entitled to notification of program experiments that might affect them, as well as protection from harmful interference that such experiments might cause to them. The *R&O* specified that for program license experiments that may affect critical service bands (*i.e.* bands used for the provision of commercial mobile services, emergency notifications, or public safety purposes), the program licensee must take the additional steps of developing a specific plan to avoid causing harmful

[67] 47 C.F.R. §2.803(c) states, "Exceptions. The following marketing activities are permitted prior to equipment authorization: (1) Activities under product development and market trials conducted pursuant to subpart H of Part 5."

[68] 47 C.F.R. § 5.601(c).

[69] *See R&O,* 28 FCC Rcd at 808, para. 136.

[70] The Emergency Alert System, or EAS, is a national public warning system that permits the President to communicate to the public during a national emergency and for state and local authorities to deliver important emergency information, such as AMBER alerts and weather warnings. *See* http://www.fcc.gov/pshs/services/eas.

interference to operations in those bands prior to commencing operations and providing notice to those critical service licensees who might be affected by the planned experiment.[71]

29. Sirius XM and EchoStar observe that the *NPRM* explicitly recognized that EAS participants provide emergency notifications,[72] and that the *R&O* required that any program licensee seeking to undertake an experiment in a band used for emergency notifications must develop a plan to avoid interference to emergency notification providers,[73] but that the *R&O* failed to specify that such providers include all EAS participants. Sirius XM and EchoStar contend that this failure will create confusion on the part of program license applicants and undermine the Commission's goal of avoiding interference threats to the EAS network.[74] Therefore, to avoid the possibility that program licensees may fail to notify EAS participants of their planned experiments or cause harmful interference to EAS participants, Sirius XM and EchoStar recommend that we set forth a definition of emergency notification providers that includes all EAS participants.[75] No party filed comments regarding the Sirius XM/EchoStar petition.

30. The Commission's goal throughout this proceeding has been to foster new experimental uses of the RF spectrum, while protecting authorized radio services from any harmful interference that these new uses might cause. Moreover, the Commission has recognized that an additional measure of protection must be afforded to bands used by services that are crucial to the public safety and well-being.[76] We observe that the Commission's clear intent in this proceeding has been to include all EAS participants as emergency notification providers. For example, the Commission included this discussion in the *NPRM*: ". . . Television and radio broadcast bands are used in support of the Emergency Alert System (EAS). In recognition of these vital interests, we propose to require that, for tests that affect bands use for the provision of commercial mobile services, emergency notifications, or public safety purposes on the institution's grounds, the licensee first develop a specific plan that avoids interference to these bands."[77] As Sirius XM and EchoStar observe, the *R&O* adopted the *NPRM*'s proposal that the program licensee must develop a specific plan to avoid harmful interference to operations in these critical service bands, but failed to explicitly state that emergency notification providers include all EAS participants. Accordingly, and to avoid any confusion, we are adding to Section 5.5 of our rules a definition of emergency notification providers as inclusive of all EAS participants, as set forth in Appendix A.

III. FURTHER NOTICE OF PROPOSED RULEMAKING

31. In two April 2015 filings, Medtronic observes that program licenses "may not be issued for operation on frequencies listed in Section 15.205 of the rules, which includes the 401-406 MHz Medical Device Radiocommunications Service ('MedRadio') band often employed by makers of implanted and body-worn medical devices."[78] Medical testing licensees, on the other hand, may use those

[71] *See R&O,* 28 FCC Rcd at 781-82, para. 62.

[72] *See NPRM,* 25 FCC Rcd at 16556, para. 31.

[73] *See R&O,* 28 FCC Rcd at 779-80, para. 59.

[74] For example, Sirius and EchoStar maintain that interference to the Sirius signal would be particularly detrimental because of Sirius's role as one of only three non-broadcast entities designated as Primary Entry Point (PEP) stations in ensuring reliable distribution of EAS messages to other PEP stations. Sirius and EchoStar Petition at 7-8.

[75] See Sirius and EchoStar Petition at 2-8.

[76] *See, e.g., R&O,* 28 FCC Rcd at 781-82, para. 62.

[77] *See NPRM,* 25 FCC Rcd at 16556, para. 31 (footnotes omitted).

[78] *See* Medtronic Ex Parte Comments, filed April 1, 2015, at 2; and Medtronic Ex Parte Comments, filed April 16, 2015, at 2.

frequencies, if they comply with applicable service rules.[79] Medtronic therefore argues that this disparity in frequencies contributes to program licensees being less flexible than medical testing licensees.[80]

32. As discussed in the MO&O, basic medical research and experimentation would be conducted under a program (or conventional) license by any manufacturer of RF-based medical devices, whether that manufacturer is eligible for a medical testing license or not.[81] The Commission created the program experimental license to reduce regulatory delay and uncertainty and to promote innovation.[82] A program license is granted for a five year term and allows the licensee to conduct multiple unrelated experiments within a broad range of frequencies. Because researchers can modify the scope of their experiments without having to obtain Commission permission to do so, the flexibility provided will accelerate innovation in RF technology, including RF-based medical devices. However, the program license rules do not permit experimentation in frequency bands that are restricted under Section 15.205(a) to protect the many safety-of-life and passive services that operate in these bands.[83]

33. Medtronic rightly points out that the 401-406 MHz band is a restricted band under Section 15.205(a) and is not available for basic research under the program license rules. However, the 401-406 MHz band is used for implanted and body worn medical devices under the Part 95 MedRadio rules. Consequently, manufacturers of certain RF-based medical devices cannot take advantage of the benefits provided by a program license to advance innovation in this area, even though the devices they ultimately develop could be authorized for use under our rules. Because clinical trials conducted under the medical testing license or as a market trial may be tested in these bands,[84] we see no reason to impose greater frequency restrictions on program licensees conducting basic research on the same devices.

34. Accordingly, we propose to modify the rules for program licenses to permit experimentation on frequencies listed in Section15.205(a) of our rules, provided that – comparable to the rules for medical testing licenses – the device being tested is designed to comply with all applicable service rules in Part 18, Industrial, Scientific, and Medical Equipment; Part 95, Personal Radio Services Subpart H – Wireless Medical Telemetry Service or Part 95, Subpart I – Medical Device Radiocommunication Service. The proposed rule changes are shown in Appendix B. These changes would establish parity between all qualified medical device manufacturers for conducting basic research and clinical trials with RF-based medical devices (as defined in Section 5.402(b)[85]) as to permissible frequencies of operation.

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[79] The rules for medical testing licenses are contained in Part 5, Subpart F. Section 5.403(b) states that "[l]icensees may use frequencies listed in § 15.205(a) of this chapter if the device under test is designed to comply with all applicable service rules in part 18, Industrial, Scientific, and Medical Equipment; part 95, Personal Radio Services subpart H—Wireless Medical Telemetry Service; or part 95, subpart I—Medical Device Radiocommunication Service." *See* 47 C.F.R. §5.403(b).

[80] *See* Medtronic April 16, 2015 Comments at 2.

[81] *See supra* para. 13, n. 32.

[82] *See R&O*, 28 FCC Rcd at 769, para. 31.

[83] *See R&O*, 28 FCC Rcd at 779, para. 56.

[84] *See* 47 C.F.R. §§5.403(b), 5.602(b).

[85] Section 5.402(b) states: "Medical testing experimental radio licenses are for testing in clinical trials medical devices that use RF wireless technology for diagnosis, treatment, or patient monitoring for the purposes of, but not limited to, assessing patient compatibility and usage issues, as well as operational, interference, and RF immunity issues. Medical testing is limited to testing equipment designed to comply with the rules in part 15, Radio Frequency Devices; part 18, Industrial, Scientific, and Medical Equipment; part 95, Personal Radio Services subpart H – Wireless Medical Telemetry Service; or part 95, subpart I – Medical Device Radiocommunication Service." *See* 47 C.F.R. §5.402(b).

IV. PROCEDURAL MATTERS

A. Memorandum Opinion and Order

35. *Regulatory Flexibility Certification*. The Regulatory Flexibility Act (RFA)[86] requires that agencies prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that "the rule will not have a significant economic impact on a substantial number of small entities."[87] We hereby certify that the rule revisions set forth herein will not have a significant economic impact on a substantial number of small entities for the following reasons: (1) Our modification of Section 5.85(a) essentially restores that rule to what existed prior to initiation of this proceeding, but with the further modification that permits use of passive service bands by compliance testing licensees, as was explicitly authorized in the *R&O*. As explained above, the prohibitions adopted in the rules appendix of the *R&O* was over-inclusive – the stated intent in this proceeding was to prohibit experimental use of the passive bands only by program and medical testing licensees and in product development and market trials. Restoring the rule to allow for the grant of conventional experimental licenses that use the passive bands, which had been permitted for many years prior to adoption of the *R&O*, as well as permitting use of these bands by new compliance testing licensees, will not have an adverse impact on any small entities. (2) Denying FDA sponsors and sponsor-investigators eligibility for medical testing licenses in Section 5.402 of our rules will not adversely impact small entities, as they will still have the ability to conduct clinical medical trials under the auspices of a product development trial, or under a program license in cases in which the Commission establishes an innovation zone for a clinical trial. (3) Clarifying that some cost reimbursement for medical devices used in clinical trials is permissible under our Section 5.602 market trial rules may benefit some small entities, without adversely impacting any such entities. (4) Clarifying in Section 5.5 of our rules that all participants in the Emergency Alert System are emergency notification providers simply codifies what was adopted in the *R&O*, and will not adversely impact any small entities. The Commission will send a copy of this Memorandum Opinion and Order, including this certification, to the Chief Counsel for Advocacy of the Small Business Administration.[88] In addition, the Memorandum Opinion and Order (or a summary thereof) and certification will be published in the Federal Register.[89]

36. *Paperwork Reduction Act Analysis*. This document contains no new or modified information collection requirement that are subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. We note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4), we previously sought specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

37. *Congressional Review Act*. The Commission will send a copy of this Memorandum Opinion and Order in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. § 801(a)(1)(A).

B. Further Notice of Proposed Rulemaking

1. Ex Parte Rules

38. This proceeding shall continue to be treated as a "permit-but-disclose" proceeding in

[86] *See* 5 U.S.C. § 604. The RFA, *see* 5 U.S.C. § 601 *et seq.,* has been amended by the Contract With America Advancement Act of 1996, Pub. L. No. 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

[87] *See* 5 U.S.C. § 605(b).

[88] *Id.*

[89] *Id.*

accordance with the Commission's *ex parte* rules.[90] Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with section 1.1206(b).[91] In proceedings governed by section 1.49(f)[92] or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

2. Filing Requirements

39. Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: http://fjallfoss.fcc.gov/ecfs2/.
- Paper Filers: Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

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

  - All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
  - Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
  - U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

[90] 47 C.F.R. § 1.1200 *et seq.*

[91] 47 C.F.R. § 1.1206(b).

[92] 47 C.F.R. § 1.49(f).

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

40. Comments, reply comments, and *ex parte* submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street, S.W., CY-A257, Washington, D.C., 20554. These documents will also be available via ECFS. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.

41. For additional information on this proceeding, please contact Rodney Small of the Office of Engineering and Technology at (202) 418-2452 or Rodney.Small@fcc.gov.

3. Initial Regulatory Flexibility Certification

42. *Initial Regulatory Flexibility Certification*. The Regulatory Flexibility Act (RFA)[93] requires that an agency prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."[94] The RFA generally defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction."[95] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[96] A "small business concern" is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).[97]

43. This Further Notice of Proposed Rulemaking proposes only a single change to the rules adopted in the *R&O*, and that proposed change would merely make available to program experimental radio licensees that undertake experiments with medical devices the same frequencies that are currently available to medical testing experimental radio licensees. The entities affected by the proposed rule change are equipment manufacturers seeking to test medical equipment designed to operate in the restricted frequency bands listed in Section 15.205(a) of the rules, and such manufacturers are very limited in number. Thus, the proposal in the Further Notice will not have a substantial economic impact on a significant number of small entities.

44. The Commission therefore certifies, pursuant to the RFA, that the proposal in this Further Notice, if adopted, will not have a significant economic impact on a substantial number of small entities. If commenters believe that the proposal discussed in the Further Notice requires additional RFA analysis, they should include a discussion of these issues in their comments and additionally label them as RFA comments. The Commission will send a copy of the Further Notice, including a copy of this initial

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

[94] *See* 5 U.S.C. § 605(b).

[95] 5 U.S.C. § 601(6).

[96] 5 U.S.C § 601(3) (incorporating by reference the definition of "small business concern" in 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."

[97] 15 U.S.C. § 632.

certification, to the Chief Counsel for Advocacy of the SBA. In addition, a copy of the Further Notice and this initial certification will be published in the Federal Register.[98]

4. Initial Paperwork Reduction Act Analysis

45. This Further Notice does not contain a proposed information collection subject to the Paperwork Reduction Act of 1995, Public Law 104-13.

V. ORDERING CLAUSES

46. Accordingly, IT IS ORDERED, that, pursuant to Sections 4(i), 301, 303 and 405 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 154(i), 301, 303, and 405 and Sections 1.1, 1.2, and 1.429 of the Commission's Rules, 47 C.F.R. §§ 1.1, 1.2, and 1.429, this Memorandum Opinion and Order and Further Notice of Proposed Rulemaking IS ADOPTED.

47. IT IS FURTHER ORDERED that the petitions for reconsideration filed by Marcus Spectrum Solutions LLC; Medtronic, Inc.; and Sirius XM Radio Inc. and EchoStar Technologies Inc. ARE GRANTED, to the extent indicated above, and otherwise ARE DENIED.

48. IT IS FURTHER ORDERED that Part 5 of the Commission's Rules, 47 C.F.R. Part 5, IS AMENDED, as set forth in Appendix A. These revisions will take effect 30 days after publication of this Memorandum Opinion and Order (or a summary thereof) in the *Federal Register*.

49. IT IS FURTHER ORDERED that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this Further Notice of Proposed Rule Making, including the Initial Regulatory Flexibility Certification to the Chief, Counsel for Advocacy of the Small Business Administration.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch

Marlene H. Dortch
Secretary

[98] *See* 5 U.S.C. § 605(b).

APPENDIX A

Rules

For the reasons set forth in the preamble the Federal Communications Commission amends Part 2 and Part 5 of the Code of Federal Regulations to read 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 2.803 is amended by revising paragraph (c)(1) to read as follows:

§2.803 Marketing of radio frequency devices prior to equipment authorization.

* * * * *

(c) * * *

(1) Activities under market trials conducted pursuant to subpart H of part 5.

* * * * *

PART 5— EXPERIMENTAL RADIO SERVICE

3. The authority citation for part 5 continues to read as follows:

Authority: Secs. 4, 302, 303, 307, 336 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 302, 303, 307, 336. Interpret or apply sec. 301, 48 Stat. 1081, as amended; 47 U.S.C. 301.

4. Section 5.5 is amended by adding a new definition to read as follows:

§ 5.5 Definition of terms.

* * * * *

Emergency notification providers. All participants in the Emergency Alert System, as identified in Section 11.1 of this chapter.

* * * * *

5. Section 5.85 is amended by revising paragraph (a) to read as follows:

§ 5.85 Frequencies and policy governing their assignment.

(a)(1) Stations operating in the Experimental Radio Service may be authorized to use any Federal or non-Federal frequency designated in the Table of Frequency Allocations set forth in part 2 of this chapter, provided that the need for the frequency requested is fully justified by the applicant. Stations authorized under Subparts E and F are subject to additional restrictions.

(2) Applications to use any frequency or frequency band exclusively allocated to the passive services (including the radio astronomy service) must include an explicit justification of why nearby bands that have non-passive allocations are not adequate for the experiment. Such applications must also

state that the applicant acknowledges that long term or multiple location use of passive bands is not possible and that the applicant intends to transition any long-term use to a band with appropriate allocations.

* * * * *

6. Section 5.402 is amended by adding paragraph (c) to read as follows:

§ 5.402 Eligibility and usage.

*****

(c) Marketing of devices (as defined in § 2.803(a) of this chapter) is permitted under this license as provided in § 5.602.

APPENDIX B

Proposed Rules

For the reasons set forth in the preamble the Federal Communications Commission proposes to amend Part 5 of the Code of Federal Regulations to read as follows:

PART 5— EXPERIMENTAL RADIO SERVICE

1. The authority citation for part 5 continues to read as follows:

Authority: Secs. 4, 302, 303, 307, 336 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 302, 303, 307, 336. Interpret or apply sec. 301, 48 Stat. 1081, as amended; 47 U.S.C. 301.

2. Section 5.303 is amended to read as follows:

§ 5.303 Frequencies.

(a) Licensees may operate in any frequency band, including those above 38.6 GHz, except for frequency bands exclusively allocated to the passive services (including the radio astronomy service). In addition, licensees may not use any frequency or frequency band below 38.6 GHz that is listed in § 15.205(a) of this chapter.

(b) Exception: Licensees may use frequencies listed in § 15.205(a) of this chapter for testing medical devices (as defined in § 5.402(b) of this chapter), if the device is designed to comply with all applicable service rules in Part 18, Industrial, Scientific, and Medical Equipment; Part 95, Personal Radio Services Subpart H – Wireless Medical Telemetry Service; or Part 95, Subpart I – Medical Device Radiocommunication Service.