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6712-01

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 5

[**ET Docket Nos. 10-236, 06-155; FCC 15-76**]

Radio Experimentation and Market Trials

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes to modify the rules for program experimental licenses to permit experimentation for radio frequency (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. This proposal is designed to establish parity between all qualified medical device manufacturers for conducting basic research and clinical trials with RF-based medical devices as to permissible frequencies of operation.

DATES: Comments must be filed on or before **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]** and reply comments must be filed on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: You may submit comments, identified by ET Docket Nos. 10-236 and 06-155, by any of the following methods:

- Federal Communications Commission's Web Site: http://apps.fcc.gov/ecfs/. Follow the instructions for submitting comments.

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

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

FOR FURTHER INFORMATION CONTACT: Rodney Small, Office of Engineering and Technology, (202) 418-2452, e-mail: Rodney.Small@fcc.gov., TTY (202) 418-2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Further Notice of Proposed Rulemaking (FNPRM), ET Docket Nos. 10-236 and 06-155, FCC 15-76, adopted July 6, 2015, and released July 8, 2015. 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 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 e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Summary of Further Notice of Proposed Rulemaking

1. In two April 2015 filings, Medtronic, Inc. (Medtronic) observes that program licenses "may not be issued for operation on frequencies listed in § 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." Medical testing licensees, on the other hand, may use those frequencies, if they comply with applicable service rules. Medtronic therefore argues that this disparity in frequencies contributes to program licensees being less flexible than medical testing licensees.

2. As discussed in the companion Memorandum Opinion & Order in this proceeding, 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. The Commission created the program experimental license to reduce regulatory delay and uncertainty and to promote innovation. 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 § 15.205(a) of the Commission's Rules to protect the many safety-of-life and passive services that operate in these bands.

3. Medtronic rightly points out that the 401-406 MHz band is a restricted band under § 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 the Commission's rules. Because clinical trials conducted under the medical testing license or as a market trial may be tested in these bands, the Commission sees no reason to impose greater frequency restrictions on program licensees conducting basic research on the same devices.

4. Accordingly, the Commission proposes to modify the rules for program licenses to permit experimentation on frequencies listed in §15.205(a) of the Commission's 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 below. 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 § 5.402(b) of the Commission's Rules) as to permissible frequencies of operation.

PROCEDURAL MATTERS

A. Ex Parte Rules

5. This proceeding shall continue to be treated as a "permit-but-disclose" proceeding in accordance with the Commission's ex parte rules. 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 § 1.1206(b). In proceedings governed by § 1.49(f) 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.

B. Initial Regulatory Flexibility Certification

6. The Regulatory Flexibility Act (RFA) 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." The RFA generally defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. 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).

7. This FNPRM proposes only a single change to the rules adopted in the Report and Order in this proceeding (78 FR 25138, April 29, 2013), 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 § 15.205(a) of the Commission's rules, and such manufacturers are very limited in number. Thus, the proposal in the FNPRM will not have a substantial economic impact on a significant number of small entities.

8. The Commission therefore certifies, pursuant to the RFA, that the proposal in this FNPRM, 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 FNPRM 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 FNPRM, including a copy of this initial certification, to the Chief Counsel for Advocacy of the SBA. In addition, a copy of the FNPRM and this initial certification will be published in the Federal Register.

9. **Initial Paperwork Reduction Act Analysis:** This FNPRM does not contain a proposed information collection subject to the Paperwork Reduction Act of 1995, Public Law 104-13.

10. **Comment Filing Instructions:** 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 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.

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). 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.

ORDERING CLAUSES

11. Pursuant to section 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 § 1.1, 1.2, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.2, and 1.429, this Further Notice of Proposed Rulemaking IS ADOPTED.

12. 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.

List of Subject in 47 CFR Part 5

Radio, Reporting and recordkeeping requirements.

FEDERAL COMMUNICATIONS COMMISSION.

Marlene H. Dortch,
Secretary.

Proposed Rule Change

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 5 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 revised 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.

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