

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
2006 Biennial Review of Telecommunications
Regulations – Part 2 Administered by the Office
of Engineering and Technology (OET)

ET Docket No. 10-236

ET Docket No. 06-155

SECOND REPORT AND ORDER

Adopted: June 29, 2016

Released: June 30, 2016

By the Commission:

1. In the Memorandum Opinion and Order (Order) and Further Notice of Proposed Rulemaking (Further NPRM) in this proceeding, the Commission proposed to modify its Part 5 experimental licensing rules to permit program experimental radio licensees (program licensees) to operate on the restricted bands of operation listed in Section 15.205(a) of its rules. More specifically, the Commission proposed to permit program licensees to experiment on those frequencies with 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, or MedRadio). We adopt this proposal, which facilitates access to spectrum that can be used under a program experimental radio license (program license), to improve the utility of this type of licensing scheme for those entities experimenting with RF-based medical devices, and thereby help to advance innovation in this area.

2. Background. In 2013, the Commission established three new kinds of experimental licenses designed to benefit the development of new technologies and expedite their introduction to the marketplace. One of these licenses is the medical testing license, under which health care facilities are

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; Memorandum Opinion and Order and Further Notice of Proposed Rulemaking, 30 FCC Rcd 7446 (2015); Erratum, 30 FCC Rcd 8394 (2015).

2 Section 15.205(a) lists bands in which only spurious emissions from (low power) Part 15 radio frequency (RF) devices are permitted; 47 C.F.R. § 15.205(a). Those bands are restricted due to the sensitive nature of the safety-of-life and passive services that operate there, which warrant special attention from co-channel users to prevent possible harmful interference to those services.

3 Order and Further NPRM, 30 FCC Rcd at 7446-47, paras. 2-3.

4 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

(continued....)

authorized to use spectrum in conducting clinical trials of medical devices that use RF wireless technology. Such medical devices could be used for medical diagnosis, treatment, or patient monitoring.<sup>5</sup> The Commission also created the program experimental license, which is available to qualified colleges and universities with graduate research programs in engineering that are accredited by the Accreditation Board for Engineering and Technology; research laboratories; hospital or health care institutions; manufacturers of RF equipment; and manufacturers that integrate RF equipment into their end products.<sup>6</sup>

3. In the *Order*, the Commission declined to expand the eligibility for medical testing experimental licenses to include entities other than hospitals and health care institutions. The Commission explained that other entities, such as medical device manufacturers, could instead conduct clinical trials under a Part 5 market trial license or at a specific geographic area designated by the Commission as an innovation zone.<sup>7</sup> The Commission also explained that since the medical testing experimental 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.<sup>8</sup> However, in declining to expand the eligibility for medical testing licenses, the Commission was unable to resolve a concern raised by Medtronic, Inc. (Medtronic).

4. The Commission explained in the *Further NPRM* that Medtronic pointed to a disparity in the frequencies used by medical testing experimental licensees and program licensees.<sup>9</sup> Specifically, Medtronic noted that the restricted frequencies listed in Section 15.205(a)—which includes the 401-406 MHz Medical Device Radiocommunications Service (MedRadio) band often employed by makers of implanted and body-worn medical devices—are available to medical testing experimental licensees conducting clinical trials, but these frequencies are not available to program licensees for basic research and experimentation. As a result, Medtronic argued, program licenses are less flexible than medical testing experimental licenses.<sup>10</sup> The Commission agreed and proposed to modify rule Section 5.303 for program licenses to permit experimentation with medical devices (as defined in Section 5.402(b)<sup>11</sup>) on frequencies listed in Section 15.205(a) of our rules, provided that – comparable to the rules for medical testing licenses – the medical 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 –

(Continued from previous page) \_\_\_\_\_

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).

<sup>5</sup> 47 C.F.R. §§ 5.54(d), 5.402.

<sup>6</sup> 47 C.F.R. § 5.302.

<sup>7</sup> *Order and Further NPRM*, 30 FCC Rcd at 7453-7454, paras. 17-18. *See also* 47 C.F.R. §§ 5.5, 5.313, 5.602.

While a program license can be used for a clinical trial if the Commission declares a specific geographic area to be an “innovation zone” for the purpose of conducting such a trial (30 FCC Rcd at 7454, para. 18), the primary purpose of a program license is basic research and experimentation.

<sup>8</sup> *Order and Further NPRM*, 30 FCC Rcd at 7451, para. 14, n. 32.

<sup>9</sup> *Order and Further NPRM*, 30 FCC Rcd at 7458-7459, para 31.

<sup>10</sup> *Id.*

<sup>11</sup> 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.” 47 C.F.R. §5.402(b).

Wireless Medical Telemetry Service; or Part 95, Subpart I – Medical Device Radiocommunication Service.

5. Only Medtronic filed in response to the *Further NPRM*, supporting the proposed rule and stating: “By making the proposed change, the Commission will help ameliorate the disparity between those medical device manufacturers eligible for Medical Testing Experimental Licenses and those eligible for Program Experimental Licenses.”<sup>12</sup>

6. *Discussion.* We modify Section 5.303 of our rules for program licenses to permit experimentation in the restricted frequency bands for medical devices that comply with the service rules in Part 18, Part 95 Subpart H, or Part 95 Subpart I. As the Commission observed in the *Further NPRM*, because clinical trials conducted under the medical testing experimental license or as a market trial may be tested in these restricted bands, there is no reason to impose greater frequency restrictions on program licensees conducting basic research on the same devices.<sup>13</sup> This rule change also will establish parity between all qualified medical device manufacturers and developers—whether they are health care institutions or medical device manufacturers—as to permissible frequencies of operation for conducting basic research and clinical trials with RF-based medical devices.<sup>14</sup> For example, some health care institutions conduct medical device research and development programs, as well as clinical trials, and thus are eligible for a program license for basic research and a medical testing license for clinical trials. On the other hand, medical device manufacturers that are not health care institutions are eligible for program licenses for basic research purposes, but not eligible for medical testing experimental licenses for conducting clinical trials of their products; instead they would conduct clinical trials under a market trial license or at a designated innovation zone. The rule change we adopt here will result in significant flexibility for all qualified entities to undertake a variety of medical experiments, irrespective of whether they qualify for a medical testing license. Accordingly, because we find that the proposal will serve the public interest by promoting medical innovation with no detriment to the public, we adopt it. Revised Section 5.303 of our rules is set forth in the Rules Appendix.

7. *Regulatory Flexibility Certification.* The Regulatory Flexibility Act (RFA)<sup>15</sup> 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.”<sup>16</sup> Modification of Section 5.303 of the Commission’s Rules establishes parity between all qualified medical device manufacturers as to permissible frequencies of operation for conducting basic research and clinical trials with RF-based medical devices. The Commission previously determined that “[t]he 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 limited in number,” and certified that the proposed rules would not have a significant economic impact on a substantial number of small entities.<sup>17</sup> We received no comments that addressed this determination or that claimed that the proposal requires additional RFA analysis. We therefore certify that the rule revisions set forth herein will not have a significant economic impact on a substantial number of small entities. The Commission will send a copy of this Second Report and Order, including this certification, to the Chief Counsel for Advocacy of the Small Business Administration.<sup>18</sup> In

---

<sup>12</sup> See *Medtronic Ex Parte*, filed October 28, 2015, at 1.

<sup>13</sup> *Order and Further NPRM* at 7459, para. 33.

<sup>14</sup> *Id.* at 7459, para. 34.

<sup>15</sup> 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).

<sup>16</sup> 5 U.S.C. § 605(b).

<sup>17</sup> *Order and Further NPRM* at 7462, paras. 43-44.

addition, the Second Report and Order (or a summary thereof) and certification will be published in the Federal Register.<sup>19</sup>

8. *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.

9. *Congressional Review Act.* The Commission will send a copy of this Second Report 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).

10. Accordingly, IT IS ORDERED, that, pursuant to Sections 301 and 303 of the Communications Act of 1934, as amended, 47 U.S.C. §§ 301 and 303, and Sections 1.1 and 1.425 of the Commission's Rules, 47 C.F.R. §§ 1.1, 1.425, this Second Report and Order IS ADOPTED.

11. IT IS FURTHER ORDERED that Part 5 of the Commission's Rules, 47 C.F.R. Part 5, IS AMENDED, as set forth in the Rules Appendix. These revisions will be effective [**30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**] of this Second Report and Order (or a summary thereof).

12. IT IS FURTHER ORDERED that, if no applications for review are timely filed, this proceeding SHALL BE TERMINATED and the docket CLOSED.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch  
Secretary

(Continued from previous page) \_\_\_\_\_

<sup>18</sup> *See* 5 U.S.C. § 605(b).

<sup>19</sup> *Id.*

**RULES APPENDIX**

For the reasons set forth in the preamble the Federal Communications Commission amends 47 C.F.R. part 5 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.