Federal Communications Commission
Washington, D.C. 20554

July 19, 2016

DA 16-820

Ms. Cheryl A. Tritt
Mr. Phuong Pham
Wilkinson Barker Knauer, LLP
1800 M Street, NW, Suite 800N
Washington, D.C. 20036

RE: The Alfred Mann Foundation for Scientific Research, Request for Waiver of Section 15.205 of the Commission's Rules, ET Docket No. 16-94

Dear Ms. Tritt and Mr. Pham:

The Office of Engineering and Technology (OET) is granting the request of The Alfred Mann Foundation for Scientific Research (AMF) for waiver of Section 15.205(a) of the Commission's rules to allow it to obtain Commission certification for and to market the first-generation implantable myoelectric sensor (IMES) system as an unlicensed device under Part 15 of the Commission's rules. In the waiver request filed on February 4, 2016,[1] you state that the IMES system is medically implanted and designed to allow amputees to have more intuitive control of their prosthetic devices by wirelessly controlling electro-myographic (EMG) sensors implanted in specific muscles of the amputee to collect and transmit EMG data, which is then analyzed and used to control the prosthetic device.[2] You indicate that the IMES system is an innovative improvement over other available types of EMG sensors that are typically body-worn (*i.e.*, placed on the skin) which could pick up EMG signals from more than one muscle at a time, thereby degrading the performance of commercially available prosthesis control systems and frustrating their users.[3]

Specifically, you request a waiver of the provisions of Section 15.205(a) to allow the IMES system to transmit data in the 94.6-157.4 kHz frequency band during start-up modes lasting less than one second in order to configure the implanted sensors, thus generating non-spurious emissions from this unlicensed device in the restricted 90-110 kHz frequency band which is prohibited under the rules.[4] You are requesting this waiver only for first-generation

[1] Alfred Mann Foundation for Scientific Research Request for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Implantable Devices Operating in the 90-110 kHz Restricted Band (AMF Request) dated February 4, 2016, from Cheryl Tritt and Phuong Pham, Wilkinson Barker Knauer, LLP.
[2] AMF Request at 3.
[3] *Id.*
[4] 47 C.F.R. § 15.205(a) prohibits Part 15 devices to generate signals other than spurious emissions in specific "restricted" frequency bands employed by radio services that must function using extremely low received signal levels, as a nature of their operation.

IMES systems that are currently under Food and Drug Administration's (FDA) review and are expected to receive FDA approval by October 2016. You argue that requiring a redesign of these first-generation systems would delay the FDA approval process for both first- and future-generation IMES systems, because FDA approval of new, next-generation IMES devices relies heavily upon approval of the first-generation devices. You also confirm that future-generation IMES systems will be redesigned to operate on a different, non-restricted frequency to comply with the rules.[5] You affirm that strict compliance with Section 15.205(a) for these first-generation IMES systems would complicate the manufacturing and testing process, impede the FDA approval process and delay the commercial introduction of these innovative medical devices, thereby depriving amputees and the public of the important benefits offered by early commercial availability of new first-generation IMES devices.[6]

You explain that the IMES system uses tiny sensors implanted directly into the muscles of the amputee to control the robotic prosthetic limb. The EMG signals are transmitted wirelessly from the muscles to the controller via a radio-frequency (RF) coil that wraps around the residual limb where the sensors are implanted. The controller then interprets the EMG signals and commands the prosthesis to perform the intended movement. You indicate that during normal and other modes of operation (*e.g.*, fitting and surgical modes), the IMES system transmits and receives data communications at 121 kHz. However, during the start-up mode lasting less than one second, the IMES controller and coil transmit data in the 94.6-157.4 kHz band to configure the implanted sensors, thus resulting in non-spurious emissions in the 90-110 kHz restricted band.[7]

You submit that grant of the requested waiver would not cause harmful interference to primary users of the 90-110 kHz band because the federal government's LORAN-C radionavigation system, authorized for primary use of the 90-110 kHz band, has been permanently discontinued,[8] as noted by the Commission in granting other waivers of Section 15.205(a) in regard to this frequency band.[9] Moreover, you argue that, in the event that future federal government systems may be deployed in the 90-110 kHz band, the IMES system poses little or no risk of harmful interference to those hypothetical operations, because its operations in this band are limited only to the start-up mode lasting less than one second when implanted sensors are configured, and more importantly, the IMES system's low-power transmissions have a maximum operating range of approximately four (4) inches.[10] Nevertheless, we note that the U.S. Coast Guard is authorized to transmit 500-540 kW in this band at eight locations[11], and is

[5] AMF Request at 2.
[6] AMF Request at 7.
[7] *Id.*, at 3.
[8] *See LORAN-C Closure*, http://www.jproc.ca/hyperbolic/loran_c_closure.html (noting permanent discontinuance of LORAN-C operations in the United States, as of February 8, 2010). *See also, Boston Scientific Corp. Request for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices That Operate in the 90-110 kHz Band*, Order, 26 FCC Rcd 11405 (2011), at fn. 13.
[9] AMF Request at 6, citing *Boston Scientific Corp. Request for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices That Operate in the 90-110 kHz Band*, Order, 27 FCC Rcd 13256 (2012).
[10] AMF Request at 7.
[11] Wildwood NJ, Gillette WY, George WA, Havre MT, Dana IN, Fallon NV, Boise City OK and Las Cruces NM.

currently doing so from Wildwood, NJ under a cooperative research and development agreement for purposes of position, navigation and timing testing. These transmissions may be expanded at any time under this agreement to include the other authorized station locations.

To support your request, you state that the IMES system offers substantial health and other public interest benefits by providing amputees with more intuitive control over their prosthetic devices, thus restoring limb movement with greater ease and reliability and assisting amputees with routine activities such as eating and walking, thereby allowing them to become more self-sufficient. You argue that these benefits, in turn, could reduce the costs of health care or in-home care for patients, while substantially improving their quality of life.[12] You also indicate that AMF holds an experimental license to test and develop its first-generation IMES system in an ongoing clinical trial at the Walter Reed National Military Medical Center.[13]

We are authorized to grant a waiver under section 1.3 of the Commission's rules if the petitioner demonstrates good cause for such action.[14] Good cause, in turn, may be found and a waiver granted "where particular facts would make strict compliance inconsistent with the public interest."[15] To satisfy this public interest requirement, the waiver cannot undermine the purposes of the rule, and there must be a stronger public interest benefit in granting the waiver than in applying the rule.[16]

We find that a waiver of Section 15.205(a) of the Commission's rules for the first-generation IMES system is warranted. This is a compelling situation, in which technology will improve the quality of life for amputees based on speedy approval by the FDA for this first-generation design. Accordingly, there is good cause for granting this waiver and it is in the public interest to do so. A grant of this waiver would not undermine the underlying purpose of the rules. Section 15.205 of the Commission's rules for unlicensed radio devices prohibits intentional radiators from operating in certain sensitive or safety-related frequency bands that are designated as "restricted bands," which are bands employed by radio services that must function, as a nature of their operation, using extremely low received signal levels. The intended purpose of this rule is to avoid interference to primary users of the restricted bands. Here, the primary use of the 90-110 kHz restricted band was the federal government's LORAN-

[12] *Id.*, at 6.
[13] AMF, FCC Experimental Radio Station Construction Permit and License, File No. 0672-EX-PL-2015, Call Sign W12XBL (granted Dec. 8, 2015).
[14] 47 C.F.R. § 1.3. *See also ICO Global Communications (Holdings) Limited v. FCC*, 428 F.3d 264 (D.C. Cir. 2005); *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164 (D.C. Cir. 1990); *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969).
[15] *Northeast Cellular*, *supra* at 1166; *see also ICO Global Communications*, *supra* at 269 (quoting *Northeast Cellular*); *WAIT Radio*, *supra* at 1157-59.
[16] *See, e.g.*, *WAIT Radio*, 418 F.2d at 1157 (stating that even though the overall objectives of a general rule have been adjudges to be in the public interest, it is possible that application of the rule to a specific case may not serve the public interest if an applicant's proposal does not undermine the public interest policy served by the rule); *Northeast Cellular*, 897 F.2d at 1166 (stating that in granting a waiver, an agency must explain why deviation from the general rule better serves the public interest than would strict adherence to the rule).

C system which ceased operation in 2010.[17] Moreover, the IMES system's transmissions in this restricted band are limited only to the start-up mode lasting less than one second, since normal and other operational modes are conducted at 121 kHz, which is not a restricted frequency. In addition, the IMES system's extremely low-power and short duration of the transmissions (less than one second only during start-up) would pose virtually no significant risk of harmful interference even if LORAN-C were operating. Thus, granting this waiver will not undermine the purpose of the rule to avoid causing harmful interference to primary users of the band. Also, there is a stronger public interest benefit in granting this waiver. By facilitating a faster commercial introduction of an innovative medical device, the quality of life for people with loss of limbs in the U.S. would be improved while potentially reducing the cost of health care.

We conclude that, given the IMES device's intended use and its limited interference potential, this request is consistent with previous waivers of this rule granted by the Office of Engineering and Technology (OET)[18] and that a waiver of Section 15.205(a) which prohibits non-spurious emissions in the 90-110 kHz frequency band is warranted. This waiver applies only to the first-generation of this specific implantable myoelectric sensor system and is limited to operation of the start-up mode lasting no more than one second; this waiver is not to be considered to apply generally to other modes of operation or other devices. In accordance with Section 15.5(b) of the Commission's rules, operation of the IMES system is subject to the condition that no harmful interference is caused and that any interference that is received by the device must be accepted, including from those stations operated by the U.S. Coast Guard.[19] Further, the IMES device must be certified to comply with all other Part 15 requirements applicable to unlicensed transmitters.

Accordingly, pursuant to the delegated authority in Sections 0.31, 0.241, and 1.3 of the Commission's Rules, 47 C.F.R. §§ 0.31, 0.241, 1.3, we waive the requirements of Section

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[17] *LORAN-C Closure*, http://www.jproc.ca/hyperbolic/loran_c_closure.html (noting permanent discontinuance of LORAN-C operations in the United States, as of February 8, 2010).

[18] *See Respironics, Inc. and Boston Scientific Corporation Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices that Operate in the 90-110 kHz Band*, Order, 21 FCC Rcd 13450, at para. 1 (OET 2006) (finding that waivers "will afford medical patients the important health benefits provided by the Respironics and Boston Scientific devices for which there currently are no reasonable alternatives and would not contravene the underlying purposes of our rules for unlicensed devices"); *Respironics, Inc. and Boston Scientific Corporation*, Order, 24 FCC Rcd 9089, at para. 1 (OET 2009) (extending term of waiver for Boston Scientific's Contak Renewal TR product line of implanted cardiac medical devices); *Respironics, Inc. and Boston Scientific Corporation*, Order, 25 FCC Rcd 13143, at para. 1 (OET 2010) (further extending term of waiver for Boston Scientific's Contak Renewal TR, Cognis, and Teligen cardiac devices); *Boston Scientific Corporation*, Order, 26 FCC Rcd 11405, at para. 1 (OET 2011) (further extending term of waiver for Boston Scientific's Contak Renewal TR, Cognis, and Teligen cardiac devices); *Boston Scientific Waiver Extension*, Order, 27 FCC Rcd 132560, at para. 1 (OET 2012) (further extending term of waiver grant).

[19] *See* 47 C.F.R. § 15.5(b). Operation of an intentional, unintentional, or incidental radiator is subject to the conditions that no harmful interference is caused and that interference must be accepted that may be caused by the operation of an authorized radio station, by another intentional or unintentional radiator, by industrial, scientific and medical (ISM) equipment, or by an incidental radiator. This information is required to be displayed under the labeling requirements in 47 C.F.R. § 15.19.

15.205(a) of our Rules, 47 C.F.R. §15.205(a), to allow the Alfred Mann Foundation to obtain Commission certification for and to market the first-generation IMES system in the restricted 90-110 kHz frequency band consistent with the terms of this order.

Sincerely,

Julius P. Knapp
Chief
Office of Engineering and Technology