DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

April 24, 2019

Mr. Julius Knapp
Chief
Office of Engineering and Technology
U.S. Federal Communications Commission
445 12th St., NW
Washington, D.C. 20554

Dear Mr. Knapp:

Thank you for your recent letter dated March 22, 2019 on behalf of the Federal Communications Commission's (FCC). Your letter requests our guidance on standards matter, particularly as new technologies such as 5G are introduced. Previously, in a letter dated February 4, 2014, you also had requested our guidance on standards related to the radiofrequency (RF) exposure principles or guidelines under which FCC should consider the newer wireless power transfer (WPT) devices that operate at frequencies for which exposure limits have not yet been specified in the FCC's rules. In light of the new technologies, you also requested FDA to identify any risks of interference to medical devices due to the use of WPT equipment.

Currently, the FCC specifies specific absorption rate (SAR) limits down to 100 kHz and maximum permissible exposure limits for electric field, magnetic field, and power density down to 300 kHz. We agree that with the increase in technology that uses frequencies below 300 kHz and even below 100 kHz, setting human exposure limits below 300 kHz and 100 kHz would better ensure the protection of the general public. The biological response to frequencies in the range below 300 kHz is complex. At the lower end of this range, electrostimulation (nerve stimulation) and induced currents predominate; at the upper end, heating is the predominant effect. Electrostimulation is a rapid biological response; therefore, the long averaging times associated with thermal-based SAR limits are not appropriate. Although they are not identical in their specifications, both the IEEE C95.1-2005 and the ICNIRP Guidelines (Health Physics, 2010) are adequate to protect the general public in this frequency range. Either of these would be an adequate model for the FCC to adopt for their rules below 300 kHz.

Regarding your request to identify any risks of interference to medical devices due to use of WPT equipment. Several types of active medical devices (e.g., implantable cardiac pacemakers, implantable deep brain stimulators (DBS), spinal cord stimulators, implantable drug infusion pumps, and body worn insulin pumps) are known to be susceptible to

electromagnetic interference (EMI) due to low frequency sources such as metal detectors, electronic anti-theft systems, and radio frequency identification (RFID) systems.[1,2,3] However, the potential for interference is greatly affected by the type of modulation and field strength. Part of the concern, regarding exposure to the lower frequency range, is that the prevailing consensus standards for external medical devices specify only limited immunity testing below 150 kHz. With the exception of testing for interference with power line magnetic fields at 50 Hz and 60 Hz, most non-implanted medical devices have not been tested for immunity below 150 kHz. Additionally, present implantable pacemakers are typically tested to the human exposure limits specified in the ICNIRP 1998 Guidelines (Health Physics 1998). Any emitter that exceeds the ICNIRP 1998 levels would be a potential source of interference to active implanted devices. Adoption of higher emissions levels may expose patients to unnecessary risk. Therefore, the most effective mitigation against EMI to active medical devices from the emissions of WPT devices is to reduce the WPT emissions and thus medical device exposure. The methods to reduce exposure should include limits on the WPT output power, designing the WPT with safety interlocks (i.e., designing the WPT source so that it can detect the presence of humans or animals and shut off or greatly reduce power output), creating exclusion zones, and recommending separation distances between the WPT emitter and any active medical devices.

With your inquiry related to safety standards, particularly as new technologies such as 5G are introduced, as you are aware, FDA is responsible for the collection and analysis of scientific information that may relate to the safety of cellphones and other electronic products. As a part of our ongoing monitoring activities, we have reviewed the results and conclusions of the recently published rodent study from the National Toxicology Program in the context of all available scientific information, including epidemiological studies, and concluded that no changes to the current standards are warranted at this time. As we have stated publicly, NTP's experimental findings should not be applied to human cell phone usage, that the available scientific evidence to date does not support adverse health effects in humans due to exposures at or under the current limits, and that the FDA is committed to protecting public health and continues its review of the many sources of scientific literature on this topic.

In summary, for standards related matter for WPT, either of IEEE C95.1-2005 and the ICNIRP Guidelines would be an adequate model for the FCC to adopt for their rules below 300 kHz.

Thank you for contacting us concerning this matter. If we can be of further assistance, please let us know. If you need any additional information, you may contact Bakul Patel, Director

---

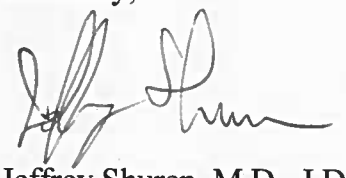
[1] FDA guidance for industry, "Labeling for Electronic Anti-Theft Systems." August 15, 2000. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070913.pdf.

[2] "Important Information on Anti-Theft and Metal Detector Systems and Pacemakers, ICDs, and Spinal Cord Stimulators", FDA Center for Devices and Radiological Health Letter to Cardiologists, Cardiac Surgeons, Neurosurgeons, and Emergency Physicians, September 28, 1998. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062288.htm.

[3] S. Seidman, K. Kainz, J. Casamento, and D. Witters, "Electromagnetic Compatibility Testing of Implantable Neurostimulators Exposed to Metal Detectors," in The Open Biomedical Engineering Journal, pp. 63-70, 2010.

for Digital Health of the Center for Devices and Radiological Health, at Bakul.Patel@fda.hhs.gov or by telephone at (301) 796-5528.

Sincerely,



Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and
Radiological Health