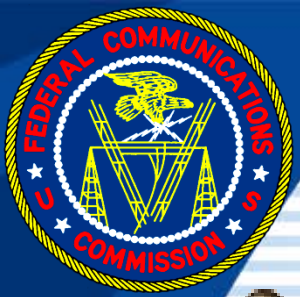


Considerations on Filing Requirements and Radiated Measurements for In-body Transmitters

Office of Engineering and Technology
Laboratory Division
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Updates (May 5, 2017) are shown in BLUE



Overview

- Review basic principles for standard measurement methods and measurement procedures in TCB application processing
- Review existing guidance for in-body transmitters
NOTE—The term “in-body transmitter” herein refers to implanted and ingestible transmitters, and transmitters attached to or adjacent to and with primary intentional radiation directed into a person’s body
- Review further considerations and concepts for in-body transmitter radiated emission measurement set-ups



Meas. Methods Background (1)

- Standard measurement methods with their associated measurement procedures are identified by FCC to facilitate:
 - Uniform device testing across labs
 - Uniform application processing across TCBs
- Equipment authorization applications processed by TCBs are required to conform with FCC rules and policies (including procedures) [§ 2.962(f)(1)]



Meas. Methods Background (2)

- Primarily for licensed-service transmitting devices, § 2.947(a) stipulates use of measurement procedures (measurement methods):
 - In OET documents [§ 2.947(a)(1)]
 - In SDO publications [e.g. ANSI, IEEE, EIA (TIA)] and that are identified by FCC as acceptable [§ 2.947(a)(2)]
 - Others identified by FCC as acceptable [§ 2.947(a)(3)]
 - DETAILED method/procedure description shall be submitted for variations from §§ 2.947(a)(1) or (a)(2) [§ 2.947(c)]
 - Additional info about method/procedure may be required (e.g. when sufficient supporting information not already provided) [§ 2.947(e)]
- For Part 15 devices, different from § 2.947, standard measurement methods are identified in § 15.31(a) [§ 2.911(c); § 2.1033(b)(6)]
 - Part 15 intentional-radiator devices (including, e.g., in-body transmitters) shall use ANSI C63.10-2013 [§ 15.31(a)(3)]



Meas. Methods Background (3)

- Where measurement methods used in an application submission are not in accordance with FCC rules, policies, and uniform procedures, before grant TCBs shall obtain acceptance from FCC for variations [consistent with § 2.962(c)(4) TCB designation requirement]
- ANSI C63.10-2013 does not provide uniform measurement methods with a human-body simulator set-up for all manner of known or possible Part 15 intentional-radiator in-body transmitters
 - Along with the cited provisions and for example § 15.209, applications for in-body transmitters submitted by TCBs must provide in-air radiated emission measurement results, or
 - Unless prior approval for measurement method variation is obtained from FCC and documented in a filing



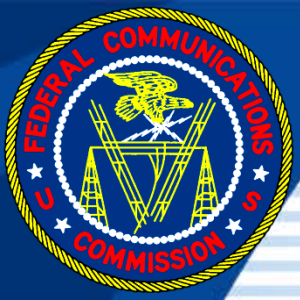
Review & Approval Guidance (1)

- For 403 MHz-band in-body **licensed** transmitters, KDB Pub. 617695 specifies FCC-approved human body simulator measurement set-up
 - Tissue-simulating liquid parameters per IEEE Std 1528-2013
- Further to FCC-TCB conference notes (e.g., 2009, 2004) and various KDB inquiry responses, specifically for radiated EMC of Part 15 implant use:
 - ANSI C63.4 tabletop test in open air, OR Part-95-like in-liquid phantom setup
 - Human torso simulator (phantom), size and shape same as Part 95
 - Maximum 2 cm from phantom wall at closest points
 - Preceding guidance originally specified for a 900 MHz pacemaker / defibrillator implant type
- Use Form-731 note code **IT** for implant and ingestible transmitters [§§ 2.962(f)(1), 2.962(c)(5)]



Review & Approval Guidance (2)

- Further to [Sec. I](#)) of KDB Pub. 388624 D02 v16r02, PAG procedure generally applies when test methods, test equipment, or requirements necessary to configure or test a device have not been established, including:
 - An existing required measurement method needs modification for testing a device, or
 - An alternative measurement method is proposed
- For Part 15 in-body transmitters intending to use measurement setups differing from those of the preceding page, before testing please submit a KDB inquiry for FCC review with:
 - Details about specific device design and operation
 - Details of proposed phantom for EMC/radio parameter measurement setup (size, shape, complex permittivity, physical representativeness rationale)
 - To support FCC RF exposure compliance determination [§§ 15.247(i), 1.1307(c) & (d), 2.1093; KDB Pub. 447498 D01], information and test results for antenna-terminal conducted output power (prefer measured, at minimum nominal/design)



QUESTIONS ?