News Letter

1. FCC于2017年12月8日发布新的KDB617965，关于在part95中心脏起搏器和除颤器的产品中，是否可以接受躯干模拟器和相等的液体材料？

Question: Is it acceptable to use the torso simulator and tissue-equivalent material previously specified in Part 95 rules for testing of MedRadio transmitters in cardiac pacemaker and defibrillator implants?

Answer: Testing of transmitters used for medical implant devices authorized under the MedRadio rules is required to determine compliance with radiated emission and EIRP limits [see Sections 95.2567, 95.2569, and 95.2579]. The MedRadio rules in the present Section 95.2569(c) (numbered as Section 95.627(g)(3)(i) when originally adopted by the Commission on March 19, 2009) require that a "Commission-approved human body simulator and test technique" be used for testing 401- 406 MHz implant transmitters.

Medical implant transmitters shall be tested for emissions and EIRP limit compliance while submersed in a medium that simulates human body tissue with the required dielectric properties. For a transmitter intended to be implanted in a human body, a test set-up as described in the following paragraph must be used to simulate operation of the implant under actual operating conditions. Simple saline solutions do not meet the above criteria.

1) For measurement purposes and to determine compliance with emission limits, the radiating characteristics of a MedRadio implant transmitter placed in a test fixture should approximate those of an implant transmitter placed in a human body.

2) An appropriate human torso simulator (phantom) for testing medical implant transmitters should consist of a cylindrical Plexiglas container, measuring 30 cm in diameter and 76 cm long, with a sidewall thickness of 0.635 cm.

3) The human torso simulator must be completely filled with a tissue-equivalent material that is sufficiently fluidic and flow around the implant without any voids.

4) The permittivity and conductivity of the tissue-equivalent material must match the dielectric parameters of the body tissue-equivalent properties in KDB Publication 865664 at 403.5 MHz. Example tissue mixture recipes are available in IEEE Std 1528-2013. The dielectric parameters must be measured and must satisfy the required target values.

5) All emission measurements shall be made using the above specification at a nominal tissue-equivalent material temperature of 20° C to 25° C.

6) A low-loss mounting grid for the implant inside the container that permits the radiating element or elements of the implant to be positioned vertically and horizontally must be used. The mounting grid shall not perturb the emission results and must also support in a fixed repeatable manner any additional implant leads associated with the therapeutic function.

7) The implant must be mounted 6 cm from the sidewall and centered vertically within the container.

8) The aforementioned liquid-filled phantom with mounting grid shall be placed on a turntable such that the implant transmitter is located at a nominal 1.5 m height above ground and at a 3 m distance from the measurement antenna. Radiated emissions measurements shall then be performed to ensure compliance with the applicable technical specifictions.
https://apps.fcc.gov/oetcf/kdb/forms/FTSSearchResultPage.cfm?id=44325&switch=P

2. FCC于2017年12月14日更新了KDB789033 D02，关于part15E UNII设备，测量程序的要求是什么呢？

Question: What are the test procedures for measuring U-NII devices subject to the requirements in Part 15, Subpart E?

Answer: The Commission initially revised the rules for U-NII devices in 2014 (FCC 14-30, ET Docket No. 13-49). Subsequently, the Commission updated some of the rules for devices operating in the U-NII-3 band on March 2, 2016 (FCC 16-24, ET Docket No. 13-49; referred to in this document as New Rules). These rules became effective on May 6, 2016.

- All new devices or already approved devices seeking to add operations under Part 15 Subpart E must meet the requirements of the latest rules.
- Permissive changes will not be permitted for devices approved under the Old Rules, unless they meet the requirements of the New Rules.
- Devices approved partially or completely under the previous rules cannot be marketed unless they meet the requirements of the New Rules in all the frequency bands of operation.
- Applications for new devices and permissive change applications for devices for approval must apply all the appropriate test procedures for such devices as described in attachment 789033 D02 General UNII Test Procedures New Rules below, including software security requirements in KDB Publication 594280 attachment 594280 D02 U-NII Device Security and the appropriate procedures from KDB Publication 905462.

789033 D02 General UNII Test Procedures New Rules v02r01

3. FCC 2017年12月其余KDB更新如下。KDB593599已被KDB703967覆盖；KDB771134已被ANSI C63.4覆盖；KDB644545已被KDB789033覆盖。

Publication Number	Question	Answer
206256	What procedures should be followed for approval of a wireless microphone?	The general equipment authorization policies that apply to the certification of a wireless microphone are provided in the attachment 206256 D01 Wireless Microphone Certification v02.
149672	What are the restrictions for certification of a transmitter that can operate under multiple rule parts?	The attached document, 149672 D01 Xmit Certified Mult Rule Parts v02 provides guidance for a radio transmitter operating under multiple rule parts. All combo devices must meet the radio parameter and RF exposure requirements. In addition there may ...
703967	What are the rules for Biomedical Telemetry Devices using the same frequency bands as VHF or UHF TV broadcast services?	Biomedical Telemetry Devices can operate under the following rules: Section 15.241 within the band 174-216 MHz (TV channels 7 to 13) and limited to Biomedical Telemetry Devices confined to an emission bandwidth of 200 kHz within the...
550599	What procedures should be used to evaluate the compliance of a Medical Body Area Network (MBAN) under Part 95?	The attachment 550599 D01 Medical Body Area Network v01r01 provides guidance on the applicable technical requirements and approval procedures for Medical Body Area Networks.

4. 2017年12月最新的协调标准已列在OJ上，并列入了五个最新的标准。

New harmonised standards under the RED OJ.
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/uri=uriserv:OJ.C_.2017.435.01.0111.01.ENG

EN 300 698 V2.2.1
Radio telephone transmitters and recei-vers for the maritime mobile service operating in the VHF bands used on inland waterways; Harmonised Stan-dard covering the essential require-ments of articles 3.2 and 3.3(g) of Directive 2014/53/EU

EN 302 054 V2.1.1
Meteorological Aids (Met Aids); Radio-sondes to be used in the 400,15 MHz to 406 MHz frequen-cy range with power levels ranging up to 200 mW; Harmo-nised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

EN 302 454 V2.1.1
Meteorological Aids (Met Aids); Radio-sondes to be used in the 1 668,4 MHz to 1 690 MHz frequency range; Harmo-nised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

EN 303 276 V1.1.1
Maritime Broadband Radiolink operat-ing within the bands 5 852 MHz to 5 872 MHz and/or 5 880 MHz to 5 900 MHz for ships and off-shore installations engaged in coordinated activities; Harmonised Standard cover-ing the essential requirements of arti-cle 3.2 of Directive 2014/53/EU

EN 303 413 V1.1.1
Satellite Earth Stations and Systems (SES); Global Navigation Satellite Sys-tem (GNSS) receivers; Radio equipment operating in the 1 164 MHz to 1 300 MHz and 1 559 MHz to 1 610 MHz frequency bands; Harmo-nised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

5. 申请FCC和ISED认证，有关上传文件时文件名取名的注意事项。

Due to regulatory agency restrictions file names cannot contain invalid characters. File names may ***not contain ", :, ?, *, %, &, +, =, <, >,), or (.*** We recommend that you rename the application exhibit files on your local computer prior to upload. This character restriction will be enforced by ACB very soon. Please plan accordingly for future uploads.