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2149 7 MAR 29 A11 :40

Reference Docket Number 2006D-0504

RTCA Recommendations to the FDA on wireless M-PED Compliance Specifications

Abstract
The proposed guidance discusses regulatory requirements for medical devices including pre-market and post market requirements. Regarding post market requirements, there is an increasing awareness of the desire and need for patients using wireless M-PEDs to safely use those devices onboard aircraft. The proposed guidance indicates the need to demonstrate "...the wireless functions will operate safely and effectively in the intended use environment." One of the intended use environments is, or should be considered to be, onboard airborne aircraft. The use of such devices onboard airborne aircraft must consider not only the safety of the patient, but also the continued safe flight and landing of the aircraft itself.

RTCA Special Committee SC-202 has been working since May of 2003, to document analysis and guidelines demonstrating safe use of portable electronic devices (PEDs) on board civil aircraft with emphasis on intentional transmitters such as devices enabled with cellular technologies, wireless RF network devices, M-PEDs, and other wireless-enabled devices such as personal digital assistants (PDAs). The committee's guidelines document DO-294B "Guidance on Allowing Transmitting Portable Electronic Devices (T-PEDs) on Aircraft" was published December of 2006.

Background
RTCA Inc. is a not-for-profit corporation formed to advance the art and science of aviation and aviation electronic systems for the benefit of the public. The organization functions as a Federal Advisory Committee and develops consensus based recommendations on contemporary aviation issues.

The United States Federal Aviation Administration (FAA) requested that RTCA Inc. form a special committee (SC-202) to present an up-to-date evaluation and policy recommendations for the use of portable electronic devices (PEDs) on-board civil aircraft with emphasis on intentional transmitters (T-PEDs) such as mobile phones, wireless RF computer network devices, and other wireless-enabled devices such as personal digital assistants (PDAs). The Terms of Reference for RTCA SC-202 are included as Attachment 1 to this letter. As part of the evaluation, current wireless Medical PED(s)(M-PED(s)) , were included in our evaluation in Document (DO) number 249B[1].

[1] DO-294B, "Guidance on Allowing Portable Electronic Devices (T-PEDs) on Aircraft" issued December 13, 2006, prepared by SC-202

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The committee included representatives from consumer electronic device manufacturers including medical implant device manufacturers, avionics manufacturers, aircraft manufacturers, airlines, aircraft operators, pilot and flight attendant associations, regulatory agencies, and related industry associations. The committee worked closely with other industry groups such as the Consumer Electronics Association as well. The committee's purpose was to evaluate the impact of the use of T-PEDs on-board aircraft on aircraft systems such as navigation and communications, surveillance, aircraft computers and sensors and to develop guidelines for safe use with respect to these aircraft systems.

Discussion

As it pertains to Medical Devices, RTCA's SC-202 primary focus was on evaluating the operational uses of external implant controllers, external readout and or implant data telemetry devices, body worn sensor devices, shallow implant depth devices and deep implant depth devices. Due to the various transmission activation modes, it should be expected that operation will occur during all phases of flight operations such as runway taxing, take-off, in flight, and landing from passengers with these systems.

As a result of our evaluation, and understanding the current FCC limitations manufactures have to work with, various transmission activation modes should be expected by aircraft operators during all phases of flight operations.

The result of DO-294, was the revision to the Federal Aviation Administrations Advisory Circular 91.21-1B[2] which in part gave the following guidance to aircraft operators:

"8. MEDICAL-PORTABLE ELECTRONIC DEVICES.

a. Medical-Portable Electronic Devices (M-PED), such as automated external defibrillators (AED), airborne patient medical telemonitoring (APMT) equipment, portable oxygen concentrators authorized by Special Federal Aviation Regulations 106, etc., should be designed and tested in accordance with section 21, Category M, of RTCA/DO-160, current edition. M-PEDs that test within the emission levels contained in this document, in all modes of operation (i.e., standby, monitor, and/or transient operating conditions, as appropriate), may be used onboard the aircraft without any further testing by the operator. Equipment tested and found to exceed the section 21, Category M, emission levels are required to be evaluated in the operator's M-PED selected model aircraft for electromagnetic interference (EMI) and radio frequency interference (RFI). All navigation, communication, engine, and flight control systems will be operating in the selected aircraft during the evaluation."

Measurements for compliance with the limits in RTCA/DO-160 should be performed by a Laboratory accredited under the A2LA or NVLAB laboratory accreditation programs for making radiated measurements. Data should be presented in terms of Effective Isotropic Radiated Power.

[2] AC 91.21-1B, "Use of Portable Electronic Devices Aboard Aircraft" issued August 25, 2006 prepared by FAA AFS-350

Recommendations

What RTCA's SC-202 is asking for, in relation to the FDA's notice, is to add language to the document that raises the awareness of the medical community of the potential when operated on board aircraft for emissions from their equipment, whether they be unintentional, fundamental or spurious, to cause interference to avionics systems operating in the aviation bands. From an airline safety point of view it would be ideal if all such medical devices were designed to meet DO-160, Category M, emission limits or follow currently defined wireless emission standards in DO-294B. Ideally, the FDA should encourage the collaboration with RTCA of medical trade organizations (e.g. AdvaMed, AAMI, Eucomed, etc.) to assess this important issue further.

RTCA's SC SC-202 encourages the FDA to incorporate in their guidance document, language to bring awareness to M-PED manufactures of transmitting and non-transmitting equipment of the potential need to evaluate their products for on-board aircraft usage. The need for evaluation of course is based on the product and the manufacturer's determination if it is expected that patients or medical personnel may use the device in a manner consistent with the usage conditions considered by SC-202.

Sincerely,

David P. Carson
Boeing Co.
RTCA SC-202 Co-Chair

James W. Fowler
US Airways, Inc.
RTCA SC-202 Co-Chair

March 28, 2007