

RADIO SPECTRUM AND TECHNICAL STANDARDS ADVISORY COMMITTEE

**Revision to HKCA 1052 Performance Specification for Medical
Implant Communication Systems**

Introduction

This paper proposes the adoption of the following revised HKCA standard:

HKCA 1052 Issue 2
Performance specification for Medical Implant Communication Systems

Current situation

2. The current version of the HKCA 1052 standard stipulates an electrical safety requirement as follows: “The equipment shall comply with the safety and electrical protection requirements set out in HKTA 2001 "Compliance Test Specification - Safety and Electrical Protection Requirements for Subscriber Telecommunications Equipment" issued by the Telecommunications Authority (TA)”.

3. Feedback has recently been received from the industry that MICS not connecting to the public telecommunications network as subscriber telecommunications equipment may be tested against a safety standard **IEC 60601-1 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”** specifically designed for this type of equipment.

Proposed revision to HKCA 1052

4. IEC 60601-1 applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems. It covers electrical safety, mechanical safety, radiation safety, protection against excessive temperatures, and so on. IEC 60601-1 is widely accepted as the de facto safety standard for medical electrical equipment. As such, it is proposed that IEC 60601-1 be incorporated in the HKCA 1052 Issue 2 as a safety standard for MICS not connecting to public telecommunications network as subscriber telecommunications equipment.

5. In addition, there is a standard EN 60601-1 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance” issued by European Committee for Electrotechnical Standardization (CENELEC), which is identical to IEC 60601-1. As such, it is proposed that EN 60601-1 also be introduced as an option.

WTO notification

6. As the proposed Issue 2 of HKCA 1052 is based on open standards, notification to the World Trade Organisation (WTO) is not necessary.

Recommendation

7. It is recommended that Issue 2 of HKCA 1052 in the Annex be adopted by the CA.

Advice sought

8. Members are invited to give comment on the recommendation above.

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