

Date : 6 November 2017



**STANDARDS**  
MALAYSIA

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**The Scheme for the Accreditation of Certification Bodies (The ACB Scheme)**  
**ACB CIRCULAR 7/2017**  
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**WITHDRAWAL OF ACB-MDQMS – SUPPLEMENTARY REQUIREMENTS FOR BODIES OPERATING MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS CERTIFICATION AND DIRECT USE OF IAF MD 9 – APPLICATION OF ISO/IEC 17021-1 IN THE FIELD OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS (ISO 13485)**

**1. Introduction**

On 9 June 2017, the International Accreditation Forum (IAF) published IAF MD 9:2017 – Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485).

Subsequently, ACB-MDQMS – Supplementary Requirements for Bodies Operating Medical Device Quality Management Systems Certification is to be withdrawn and IAF MD 9: 2017 is to be directly used.

This circular applies to all Certification Bodies (CBs) accredited to Medical Device Quality Management Systems (MDQMS).

**2. Objective**

This circular is aimed to inform all accredited MDQMS CBs on the transition arrangements to be carried out by certification bodies.

**3. Requirements**

**3.1 Accredited Certification Bodies**

- i. Certification bodies (CB) are advised to review IAF MD 9: 2017, conduct a gap analysis, train personnel, and update relevant documentation, where necessary. Certification bodies are required to document and submit to Standards Malaysia a gap analysis to IAF MD 9:2017 prior to the transition assessment.
- ii. Standards Malaysia shall assess all related accredited certification bodies against the new standard as part of the annual office assessments beginning **9 June 2018**. A verification assessment may be carried out to verify compliance against the new standard.

- iii. Findings to the new IAF MD 9:2017 shall be raised as non-conformance or observations depending on the nature of the subject matter. Corrective actions for the non-conformances shall be verified and closed out before recommendation for accreditation to MDQMS based on ISO/IEC 17021-1:2015 and IAF MD 9: 2017 can be granted.
- iv. If a certification body fails to comply with IAF MD 9:2017 by 9 June 2018, the certification body shall be suspended for a maximum of 3 months. After the suspension period, failure to take any action would result in withdrawal of accreditation of the certification body.

### **3.2 New Application:**

- i. All new applications received after **the date of publication of this circular** shall be assessed against ISO/IEC 17021-1:2015 and IAF MD 9:2017.
- ii. For existing applicants, assessments after **9 June 2018** shall be assessed against IAF MD 9:2017.

### **3.3 Extension of Scope:**

- i. Extension of scope after **the date of publication of this circular** shall be based on IAF MD 9:2017.

## **4. Validity of ACB-MDQMS**

The status of accreditation to ACB-MDQMS will remain valid until the certification body achieves the transition or until the end of the transition period, i.e 9 June 2018.

**THANK YOU**

Director of Accreditation