ACCREDITATION SCHEME FOR
MANAGEMENT SYSTEMS CERTIFICATION BODIES

CT 18

SAC CRITERIA FOR CERTIFICATION BODIES (MEDICAL DEVICES – QUALITY MANAGEMENT SYSTEMS)

CT 18, 29 March 2019
The SAC Accreditation Programme is managed by Enterprise Singapore

1 Introduction

1.1 This document specifies the supplementary SAC criteria for certification bodies on Medical devices – Quality management systems (MDQMS) to *ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes*, *a*nd is to be used with ISO/IEC 17021-1 and the applicable IAF Mandatory Documents.

2. Scope of Accreditation and Certification

2.1 The technical areas described in Annex A of IAF MD 9 shall be used to define the scope of certification and accreditation.

3 Criteria for MDQMS Auditors

3.1 A certification body shall appoint qualified auditors to conduct MDQMS audits. Auditors shall meet the criteria defined in Annex B and Annex C of IAF MD 9 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485).

4 Duration of MDQMS Audits

4.1 A certification body shall determine the MDQMS audits time defined in Annex D of IAF MD 9 for initial audits.

4.2 For integrated audits see IAF MD11. For multi-site sampling, refer to MD 9.1.5 where design, development and manufacturing sites cannot be sampled.

4.3 Annual surveillance audit duration = 1/3 of initial audit duration

4.4 Recertification audit duration = 2/3 of initial audit duration

5. Witnessed Assessment by SAC

5.1 In the case of initial assessment, the samples for witnessing of audits, priority shall be given to an audit of the higher risk class (Class C or D) of the Technical Areas covered under the scope of accreditation. For risk classification, refer to GN-13: Guidance on the Risk Classification of General Medical Devices and GN-14: Guidance on the Risk Classification of In- Vitro Diagnostic Medical Devices at the Health Sciences Authority (HSA) website.

5.2 The surveillance and reassessment shall include on-site office assessment as well as witnessing. The witnessing programme shall ensure, as a minimum, that one audit from each of the Main Technical

Areas (shown in Annex A of IAF MD9) under the scope of accreditation is witnessed within an accreditation cycle.

6 Information required on the Issued Certificate

6.1 The Certification Body shall issue certificate and state concisely the following information:

a) Unique Certificate Number

b) Certification Body Name

c) Name and Address of Certificate Holder

d) Name and Address of Site(s) covered by Certification

e) Technical Areas – Reference to Annex A of IAF MD9

f) Key Activities at Site(s) covered by Certification– such as Manufacturing (or Production)/ Design and Development/ Storage and Distribution/ Installation/ Servicing/ Provision of associated activities/ Supplier or external parties providing product *

* For example: raw materials, components, subassemblies, medical devices, sterilization services, distribution services, maintenance services

g) Certification Standard (including year of edition) – e.g. ISO 13485:2016

h) Date Issued and Expiry

6.2 Information on Product Category based on Annex A of IAF MD9 is recommended however optional.

6.3 For product owner where manufacturing (or production) is subcontracted, it is recommended to state as ‘Control of manufacturing’.