	<b>United States Accreditation, INC.</b> <b>Instruction for Medical Devices - Quality Management Systems for Certification Bodies</b>	<b>Document No:</b>	<b>USACC-IN-26</b>
		<b>Release Date:</b>	<b>01/04/2021</b>
		<b>Rev Date / No:</b>	<b>0</b>

## **1 Scope**


- 1.1 This document specifies the supplementary United States Accreditation, INC. criteria for certification bodies on Medical devices – Quality management systems (MDQMS) to ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes, and is to be used with ISO/IEC 17021-1 and the applicable IAF Mandatory Documents.
- 1.2 The technical areas described in Annex A of IAF MD 9 shall be used to define the scope of certification and accreditation.

## **2 Criteria for MDQMS Auditors**

- 2.1 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).

## **3 Duration of MDQMS Audits**

- 3.1 A certification body shall determine the MDQMS audits time defined in Clause 9.1.4 of IAF MD 9 for initial audits.
- 3.2 For initial audits, please also refer to Annex D of IAF MD 9.
  - 3.2.1 Where higher risk medical devices (Class C or D) are concerned, Stage 1 should be performed on-site.
  - 3.2.2 Stage 2 shall take place at the site(s) of the client.
- 3.3 Annual surveillance audit duration = 1/3 of initial audit duration. Please refer to Section 5 of IAF MD 5 for details.
  - 3.3.1 The certification body shall conduct surveillance audits on certified clients at least once a year.
- 3.4 Recertification audit duration = 2/3 of initial audit duration. Please refer to Section 6 of IAF MD5 for details.
- 3.5 For integrated audits, refer also to IAF MD11 in determining the audit time.
- 3.6 For multi-sites audits, refer also to IAF MD 1 in determining the audit time.

	<b>United States Accreditation, INC.</b> <b>Instruction for Medical Devices - Quality Management Systems for Certification Bodies</b>	<b>Document No:</b>	<b>USACC-IN-26</b>
		<b>Release Date:</b>	<b>01/04/2021</b>
		<b>Rev Date / No:</b>	<b>0</b>

#### **4. Sampling for MDQMS Audits**


4.1 For multi-site sampling, refer to IAF MD 1 Clause 9.1.5 where design, development and manufacturing sites cannot be sampled.

4.1.1 For single management system, also refer to IAF MD 1.

#### **5. Witnessed Assessment by United States Accreditation, INC.**

5.1 In the case of initial assessment, the samples for witnessing of audits, shall include minimum of one audit in the higher risk class (Class C or D devices per USACC-G-07 , USACC-G-13 and USACC-G-22) of the Technical Areas in each Main Technical Area covered under the scope of accreditation. For risk classification, refer to USACC-G-07 Declaration of the Scope to be Accredited for Medical and Experimental Laboratories, USACC-G-13 Flexible Scope Accreditation Guide for Experiments and Medical Laboratories, USACC-G-22 Guidelines on the Calculation of Assessment Periods (Person/Day) for Accreditation Assessments United States Accreditation, INC. website.

5.2 The surveillance and reassessment shall include on-site office assessment as well as witnessing. The surveillance office assessments and witness assessment(s), unless required by regulations, shall be conducted at least once a year. 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 prior to the expiry of accreditation. The sampling for witnessing shall give priority to higher risk technical areas.

 <b>UNITED STATES ACCREDITATION</b>	<b>United States Accreditation, INC.</b> <b>Instruction for Medical Devices - Quality Management Systems for Certification Bodies</b>	<b>Document No:</b>	<b>USACC-IN-26</b>
		<b>Release Date:</b>	<b>01/04/2021</b>
		<b>Rev Date / No:</b>	<b>0</b>


**6 Information required on the Issued Certificate**

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

<ul style="list-style-type: none"> <li>a) Unique Certificate Number</li> <li>b) Certification Body Name</li> <li>c) Name and Address of Certificate Holder</li> <li>d) Name and Address of Site(s) covered by Certification</li> <li>e) Technical Areas – Reference to Annex A of IAF MD9</li> <li>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 *</li> </ul>
<p>* For example: raw materials, components, subassemblies, medical devices, sterilization services, distribution services, maintenance services</p> <ul style="list-style-type: none"> <li>g) Certification Standard (including year of edition) – e.g. ISO 13485:2016</li> <li>h) Date Issued and Expiry</li> </ul>

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

6.3 For product owner where manufacturing (or production) is subcontracted, ‘Manufacture (or Production)’ shall be included in the overall scope statement. If design controls are included, ‘Design’ or ‘Design and Development’ shall also be included in the scope statement. Certification body shall ensure the organization has effective controls in place for the outsourced processes.

	<b>United States Accreditation, INC.</b> <b>Instruction for Medical Devices - Quality Management Systems for Certification Bodies</b>	<b>Document No:</b>	<b>USACC-IN-26</b>
		<b>Release Date:</b>	<b>01/04/2021</b>
		<b>Rev Date / No:</b>	<b>0</b>

## **7 Information Requirements**

7.1 A certification body shall provide the information (e.g. Name of company, certificate number, reason and effective date) about reduction of scope due to unmet certification requirement, suspended or withdrawn certification, to the Regulatory Authority every quarterly.

## **8 Implementation**

8.1 This instruction is a part of USACC-G-28 Guidelines for Accreditation of Conformity Assessment Bodies and USACC-P-01 Accreditation Procedure of CABs, these will be use together. Cannot be used separately.