National Accreditation Center of Iran
مرکز ملی تایید صلاحیت ایران

# MDQMS Certification bodies Assessment

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## Changes History

| Clause Numbers | Revision No | Revision Date | Summary of changes |
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## 1. Objectives

This document specifies the supplementary NACI 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.

## 2. Scope

This document is applicable for the assessment of CABs for Medical devices – Quality management systems.

## 3. Responsibilities

The NACI vice president is responsible for implementation, & the NACI President supervises adequate execution of these procedures.

## 4. References & Regulations

4.1 ISO/IEC 17011:2017 Conformity assessment -- requirements for accreditation bodies accrediting Conformity assessment bodies

4.2 The NACI accreditation Manual NACI-M00.

4.3 IAF MD 8:2020 Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)

4.4 IAF MD 9:2017 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

4.5 GN-13: Guidance on the Risk Classification of General Medical Devices

4.6 GN-14: Guidance on the Risk Classification of In- Vitro Diagnostic Medical Devices.

Note: For more information you can refer the Health Sciences Authority (HSA) website

## 5. Terms & Definitions

All terms & definitions in these procedures conform to those given in the references cited in Clause 4 above. In addition, the terms & definitions given below are applicable.

5.1 **NACI**: means the National Accreditation Center of Iran.

5.2 **CB**: Certification body applying for accreditation.

# 6. Instructions

## 6.1 Criteria for MDQMS Auditors

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).

## 6.2 Duration of MDQMS Audits:

6.2.1 For initial audits, please also refer to Annex D of IAF MD 9.

6.2.2 Where higher risk medical devices (Class C or D) are concerned, Stage 1 should be performed on-site. 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.

6.2.3 Stage 2 shall take place at the site(s) of the client.

6.2.4 Annual surveillance audit duration = 1/3 of initial audit duration. Please refer to Section 5 of IAF MD 5 for details.

6.2.5 The certification body shall conduct surveillance audits on certified clients at least once a year.

6.2.6 Recertification audit duration = 2/3 of initial audit duration. Please refer to Section 6 of IAF MD5 for details.

6.2.7 For integrated audits, refer also to IAF MD11 in determining the audit time.

6.2.8 For multi-sites audits, refer also to IAF MD 1 in determining the audit time.

## 6.3 Sampling for MDQMS Audits

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

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

## 6.4 Witnessed Assessment by NACI

6.4.1 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 GN-13 and GN-14) of the Technical Areas in each Main Technical Area 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.

6.4.2 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.

## 6.5 Information required on the Issued Certificate

6.5.1 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

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

6.5.3 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

## 6.6. Information Requirements

6.6.1 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.

**7. Related Documents**
7.1 Document control procedures NACI-P01
**7.2** Procedures on accreditation of CABs NACI-P10

**8. Forms & Records**
8.1 Document Control List form **NACI-F101**
8.2 Document Proposal or Review form **NACI –F103**
8.3 Document Distribution form **NACI- F104**
8.4 All records related to these procedures are maintained on form **NACI-F105**

**9. Recipients**
As per distribution list form **NACI –F104**

**10. Annexes**
Not applicable

**11. Withdrawn Documents**

Not applicable

## Document Control Page

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