KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

ACC-CD-53-01

Criteria for the Accreditation of Certification Bodies for ISO 13485 (Medical Devices Quality Management Systems)

Table of Contents

1 Background Information 2
1.1 Process Overview 2
1.2 Purpose 2
1.3 Scope 2
1.4 Role(s) and Responsibility: 3
2 Terms and Definitions 4
2.1 Acronyms and Abbreviations 4
2.2 Definition of Terms 4
3 Criteria 7
3.1 Requirements of Accreditation 7
3.2 Determination of Accreditation Scope 8
3.3 Human Resource Requirements 8
3.4 Determination of Audit time 9
3.5 Onsite Assessment 9
3.6 Witnessing audit plans for initial/reassessment 10
3.7 Selection of Witness Audit 10
3.8 Maintenance of Accreditation 12
3.9 Scope Extension 13
3.10 General remarks on witnessing 13
3.11 Specific Assessment Issues 14
3.12 Accreditation Standards 14
4 Associated Documents 15
5 Revision/Amendment Records 15

Approved Version

1 Background Information

1.1 Process Overview

This document applies to the accreditation of certification bodies performing certification of quality management systems in accordance with ISO 13485 for organizations involved in any stage of the medical device lifecycle, including manufacturers, sales & distribution, supply chain actors, healthcare service providers, healthcare institutions, and other relevant economic operators who are seeking accreditation from KENAS. It is intended that after four years and on a need basis the content of this document will be revised.

The requirements for accreditation are laid down in ISO/IEC 17021-1 for management system certification and ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes.

1.2 Purpose

This document has been prepared by a Technical Working Group for Medical Device Quality Management System Certification Bodies Accreditation and authorized for adoption by KENAS. It is supplementary to ISO/IEC 17021-1 which provides specific guidance on the accreditation of Certification Bodies certifying Medical Device Quality Management System MDQMS Certification Bodies and IAF MD 9 application of ISO/IEC 17021-1 in the field of medical devices quality management systems (ISO 13485) for use by KENAS assessors and by certification bodies seeking for and maintaining accreditation

1.3 Scope

This document covers the application of ISO/IEC 17021-1 for the accreditation of Medical Devices certification bodies aligning to ISO 13485.

The scope under consideration is on the certification process for a Certification Body certifying Medical Devices Management system that covers the entire medical device lifecycle which includes design, development, production, storage, distribution, installation, servicing and disposal. Additionally, this includes supporting services and suppliers

This document will be applied in conjunction with those in the Assessor Guide and Terms of Reference ACC-CD-02-01, procedure for Management and Reporting of Assessments ACC-PR-07-01, Sampling during Assessment and Internal Audits ACC-PR-03-01, Policy for Management of Extraordinary Events PL-13-01, and the Policy for dealing with objection of assessors/experts PL-30-01. Accreditation shall be based on demonstrated competence of the Medical Devices Certification Bodies in accordance with of ISO/IEC 17021-1 IAF MD 9 and ISO 13485. The scope under consideration covers the entire lifecycle of medical device from design and

Approved Version

development to production/manufacturing, distribution & logistics, installation & commissioning, storage, servicing & maintenance, decommissioning and disposal, including supporting services and suppliers.

1.3.1 Healthcare Technology Management (HTM) Certification Scope

KENAS recognizes that organizations involved in the management of medical devices within healthcare settings play a critical role in ensuring device safety, performance, and regulatory compliance.

Certification Bodies seeking accreditation for ISO 13485 certification may extend their scope to include Health Technology Management (HTM) systems, provided that such systems are directly related to the lifecycle management of medical devices.

This scope may apply to but is not limited to: Healthcare institutions (hospitals, clinics), Biomedical engineering departments, Third-party medical equipment service providers, Managed equipment service providers, Medical Device maintenance and calibration service organizations.

Certification Bodies shall ensure that the scope of certification is clearly defined and limited to medical device-related processes, including:

- Equipment planning and needs assessment
- Procurement and technical evaluation of medical devices
- Installation, commissioning, and acceptance testing
- Preventive and corrective maintenance systems
- Calibration and performance verification
- Equipment inventory and asset management systems
- Risk management related to medical device use (aligned with ISO 14971)
- Decommissioning and disposal of medical devices
- Management of outsourced technical services

The following activities are excluded and shall not be considered within the scope of ISO 13485 certification under HTM:

- Clinical decision-making and patient care
- General hospital administration
- Non-medical infrastructure (e.g., buildings, utilities not directly related to medical devices)

1.4 Role(s) and Responsibility:

The roles and responsibilities outlined below relate to the implementation of this document.

Approved Version

Role	Responsibility
Certification Department	Process owner
Manager Certification	Reviewer
Chief Manager Inspection & Verification	Recommender
Chief Executive Officer	Approval
Certification Bodies	Compliance

2 Terms and Definitions

For the purpose of this guidance document, the following terms and definitions shall apply in addition to those specified in ISO/IEC 17000 and the Kenya Accreditation Service Act Cap. 496A.

2.1 Acronyms and Abbreviations

AB	Accreditation Body
CB	Certification Body
CEO	Chief Executive Officer
CMIV	Chief Manager Inspection & Verification
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
KENAS	Kenya Accreditation Service
MC	Manager Certification
TS	Technical Specifications
MDQMS	Medical Device Quality Management System

2.2 Definition of Terms

2.2.1 Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. (ISO/IEC 17011:2017)

2.2.2 Advisory Notice

The documented and controlled communication issued by the manufacturer or authorized representative, subsequent to distribution of a medical device, in

Approved Version

accordance with applicable regulatory and quality management system requirements, to ensure continued safety, performance, and compliance.

It shall include, as applicable:

a) Communication of supplementary safety or performance information related to the medical device;
b) Instructions for continued safe use of the device;
c) Actions for modification, correction, or update of the device;
d) Instructions for return, replacement, recall, or withdrawal of the device;
e) Direction for cessation of use or destruction of the device; and
f) Traceability and linkage to post-market surveillance, vigilance reporting, or CAPA processes.

2.2.3 Authorised Representative

Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation. (ISO 13485:2016)

2.2.4 Clinical Evaluation

A Systematic, documented assessment and analysis of clinical data to verify the clinical safety, performance, and benefit–risk profile of a medical device when used as intended by the manufacturer.

It shall be based on clinical investigations, scientific literature, and/or post-market clinical data and maintained throughout the device lifecycle. (ISO 13485:2016)

2.2.5 Competence

Ability to apply knowledge, experience, and skills to achieve intended results. (ISO/IEC 17021-1)

2.2.6 Complaint

Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices. (ISO 13485:2016)

2.2.7 Distributor

Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user or other supply chain entities, without altering the device's design, intended use, or labelling.

It shall:

a) Operate within the manufacturer's authorized distribution system;

Approved Version

b) Ensure maintenance of storage, handling, and transport conditions that preserve device safety, performance, and conformity;
c) Iii. Maintain traceability of distributed devices as required by applicable regulatory requirements; and
d) Not perform activities that may affect device conformity unless explicitly authorized under a defined agreement or regulatory framework. (ISO 13485:2016)

2.2.8 Implantable Medical Devices

Medical device intended by the manufacturer to be introduced, wholly or partially, into the human body through a surgical or medical procedure and intended to remain in position for at least 30 days, or to be permanently retained within the body, unless removed by medical or surgical intervention.

It shall:

a) Be designed for long-term anatomical or functional presence within the human body requiring invasive implantation and, where applicable, explanation;
b) Maintain verified biocompatibility, structural integrity, and functional performance throughout the intended duration of use under foreseeable conditions;
c) Be subject to enhanced regulatory controls including design controls, clinical evaluation, and post-market surveillance requirements.

2.2.9 Life Cycle

All phases in the life of a medical device, from the initial conception to final decommissioning and disposal. (ISO 13485:2016)

2.2.10 Manufacturer

Natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under their name; whether or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s). (ISO 13485:2016)

2.2.11 Medical Device

Medical device instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s). (ISO 13485:2016)

2.2.12 Scope of Accreditation

The specific conformity assessment services for which accreditation is sought or has been granted.

Approved Version

2.2.13 Sterile barrier system

Minimum packaging configuration designed, validated, and maintained to provide an effective barrier against the ingress of microorganisms and particulate contamination, thereby ensuring the sterility of the medical device until the point of use. (ISO 13485:2016)

2.2.14 Technical cluster

The defined grouping of medical devices based on common technology, intended use, and risk characteristics for the purpose of classification and conformity assessment.

It shall include, as applicable:

a) Active medical devices (e.g., ventilators, patient monitors);
b) Non-active medical devices (e.g., medical furniture, consumables);
c) In vitro diagnostic medical devices (IVDs);

3 Criteria

3.1 Requirements of Accreditation

3.1.1 A Certification Body (CB) shall apply ISO/IEC 17021-1 and IAF MD 9 to be accredited to certify Medical Devices Management Systems

3.1.2 The CB shall ensure that all personnel involved in MDQMS audit activities demonstrate knowledge of ISO 13485, ISO 14971 and ability to demonstrate such knowledge in practice.

3.1.3 The CB auditors shall have knowledge of Pharmacy and Poisons Board (PPB) requirements (Kenya) CAP 244, Pharmacy and poisons rules 2022 and other relevant legal requirements as per the technical areas under review.

3.1.4 The application package includes the following:

a) Duly filled application document.
b) Corporate Profile.
c) Copy of documents demonstrating legal status.
d) Organizational chart.
e) A list of locations in which the certification body carries out its certification activities if applicable. An applicant or accredited certification body shall include all names and geographic locations of a certified client organisation covered by a certification in the certification document.
f) The activities carried out in each geographic location covered by a certification shall also be clearly specified in the certification documents.

Approved Version

g) Cross reference matrix identifying the CB's system documentation where accreditation requirements are met.
h) Management System Documents; including CB procedures and other supporting documentation which demonstrate conformity to the accreditation and/or sector scheme criteria.
i) Matrix of auditors/technical experts which identifies their qualifications for the applicable scopes, sector scheme and standards to be issued by the CB.

3.2 Determination of Accreditation Scope

3.2.1 The accreditation scope of the Certification Body shall be defined, established, and maintained in accordance with ISO/IEC 17021-1 and ISO 13485, ensuring that it reflects the defined certification activities, technical competence requirements, and applicable regulatory and conformity assessment obligations. The accreditation scope for the certification body shall be based on ISO/IEC 17021-1 and ISO 13485.

3.3 Human Resource Requirements

3.3.1 The Certification Body shall establish, document, implement, and maintain defined competence criteria for all personnel involved in the management, planning, execution, review, and certification decision activities for Medical Device Quality Management System (MDQMS) audits in accordance with ISO 13485 and applicable regulatory conformity assessment requirements. Competence criteria shall be based on defined education, training, technical knowledge, and relevant professional experience.

3.3.2 Certification Bodies seeking accreditation for HTM certification shall demonstrate:

a) Availability of auditors with biomedical engineering expertise
b) Knowledge of healthcare environments (e.g., ICU, theatre, renal units)
c) Understanding of medical device lifecycle management in operational settings
d) Competence in evaluating maintenance systems, equipment performance, and service delivery models

3.3.3 The Certification Body shall maintain controlled records demonstrating the qualification, training, competence evaluation, and professional experience of all auditors and technical experts. Auditors shall demonstrate, as a minimum, verified competence in:

a) Medical device manufacturing and regulatory conformity requirements within the defined scope;
b) Risk management principles and application in accordance with ISO 14971;

Approved Version

c) Clinical application, intended use and technical support of medical devices;
d) Clinical use environments, including conditions of use, user interface factors, and associated patient safety and operational risk considerations; and
e) Post-market surveillance (PMS) and vigilance systems, including regulatory reporting obligations.

3.3.4 Initial qualification of auditors shall include documented evaluation through witnessed audits and on-site performance assessment conducted by qualified Certification Body personnel prior to authorization for independent audit activities.

3.3.5 All personnel performing MDQMS audit activities shall establish, maintain, and continuously enhance their competence through structured Continuous Professional Development (CPD) programs. CPD activities shall include formal training, technical seminars, professional conferences, regulatory updates, peer review, and self-directed study to ensure sustained competence in alignment with applicable regulatory and conformity assessment requirements.

3.4 Determination of Audit time

The Certification body shall have procedures to determine the audit man days required for audit for initial assessment, surveillance and reassessment. The procedure shall also include the policies for estimation of audit duration for multisite organizations and transfer of certificates, as needed.

3.5 Onsite Assessment

3.5.1 During the initial assessment, the implementation of policies and procedures is assessed at the office(s) of the Certification body.

3.5.2 The on-site assessment shall be conducted at the head office and any other locations as applicable.

3.5.3 The on-site Initial assessment comprises two mandatory components to determine if the certification body should be granted accreditation:

a) Assessment of the applicant's implementation of its management system in an office assessment.
b) Assessment of the applicant's auditors – witnessed assessment

Approved Version

3.5.4 During the office assessment the team samples the files of clients and personnel to cover the scope for which accreditation is sought. This is to be determined by the Team Leader, who should apply the following guidelines:

a) Files from each of the Technical Areas certified that are a representative of the scope requested.
b) The files to be reviewed shall include at least an initial, surveillance and recertification audit for the certification body.
c) Technical Areas, which are included in the program for witnessing, may be excluded.

3.5.5 The Assessment Team Leader shall verify the composition, operations and records-of the Impartiality committee (if in place) to demonstrate how they are handling impartiality.

3.5.6 The Assessment Team Leader shall interview the chair of the impartiality committee (if in place) of the certification body or a committee meeting is witnessed or the minutes of the meeting verified.

3.5.7 In case the CB has any engagement with a consultancy body, KENAS shall verify files of this consultancy body to confirm the effectiveness of measures taken to mitigate any identified risks to impartiality.

3.6 Witnessing audit plans for initial/reassessment

3.6.1 At least two weeks before witnessing of audits the KENAS team shall be provided with the following information:

a) Documented information (e.g. Quality Manual and key procedures) of the organization to be audited by the CB
b) Competence profile of the auditors to be witnessed
c) CB Audit Plan;
d) Previous Audit report (including notes), required actions and responses from the previous audit activity;
e) In case a surveillance or recertification audit is witnessed, a copy of the ISO 13485 certificate issued by the CB

3.7 Selection of Witness Audit

3.7.1 When deciding how many and which audits are to be witnessed, a risk-based selection of audits to witness shall be applied. The priorities shall be for high-risk device manufacturers, first time certification and complex technologies, . In general, KENAS shall consider factors such as:

a) the Certification Bodies' overall performance;
b) factors such as process complexity or legislation etc. which influence the ability of the certification body to demonstrate its ability to meet the intended outcomes of the Management System;

Approved Version

c) feedback from interested parties including complaints about the certification body;
d) the results of the Certification Bodies 's internal audits;
e) scheme owner requirements, etc.;
f) changes in Certification Bodies work patterns – growth of work within a specific region or technical area;
g) previous or other office or witnessing assessment results, etc.
h) complaints, customer surveys;
i) interested parties and regulators requests;
j) the Technical areas already assessed;
k) experience from other types of accreditation of Certification Bodies;
l) previous history of the Certification Bodies' ability to manage its operations;
m) level of controls exercised by a Certification Bodies over its certification activities;
n) specific scheme requirements; and
o) national agreements with clients.

3.7.2 In addition to the office audit activities, the following witness selection rules apply for the granting and extension of accreditation of MDQMS certification to guarantee the appropriate coverage of the applicant scope

3.7.3 In the initial accreditation cycle (meaning from first surveillance to the first reassessment), KENAS shall perform at least one witnessing activity in each category. This programme will continue until the CB has demonstrated sufficient experience and performance for an enhanced programme. When this happens, KENAS shall perform at least one witnessing activity in each category, during two successive accreditation cycles. This shall be complemented with other assessment activities to guarantee that each category is assessed at each cycle. KENAS shall justify why the witnessing programme was reduced. Normally, the witnessing frequency established for a 1st cycle would be reinstated if significant changes occur in the CBs' auditor qualification process, auditing practices or results and audit personnel.

3.7.4 The first and last witnessed audits should normally not be more than 6 months apart.

3.7.5 The auditee for the audit, which will be observed, should be a reasonable representation for the requested scope of accreditation.

Approved Version

3.8 Maintenance of Accreditation

3.8.1 The implementation of the accredited certification scheme and shall be verified during surveillance assessment by KENAS.

3.8.2 The files reviewed during the maintenance of accreditation in a four-year period (accreditation cycle) shall cover all the clusters mentioned for which the CB is accredited.

3.8.3 The number of files to be reviewed for each assessment is calculated from the number of valid certificates under accreditation for each scope (approximately one fifth of the square root of the number of certificates with a maximum of fifteen (15) files).

3.8.4 For the accreditation cycle, the number of witnessed audits shall be determined based on the following factors:

a) for each technical area included in the scope of the CB; or
b) 1 per √ (number of auditors qualified for MDQMS certification).
(Whichever gives the higher number, with a maximum of ten (10))

3.8.5 When the second factor gives the higher number of witnessed audits, these shall also be spread over all clusters. This formula ensures that both a higher diversity in technical areas and a higher number of auditors will increase the number of witnessed audits.

3.8.6 In the application of the above guidelines, it shall be considered whether witnessed audits may serve for multiple scopes (e.g. by witnessing combined audits) and how many witnessed audits are performed in the other scopes.

3.8.7 The functioning of the impartiality committee (if constituted) of the Certification body is reviewed in-depth at least once during the accreditation cycle.

3.8.8 The KENAS Assessment Team Leader shall determine the method, which may include an interview (face-to-face, or telephone conversation) with a representative (non-CB) of the Committee, or the attendance to (part of) one of their meetings.

3.8.9 An accredited body that is aggrieved by a decision of the Service may, by notice in writing to the Chief Executive Officer and upon payment of the prescribed fees, appeal against the decision within twenty-one days of being notified of the decision.

3.8.10 A notice of appeal under this section shall set out the grounds of the appeal.

Approved Version

3.8.11 The Chief Executive Officer shall, within seven days of receipt of the notice, forward the notice to the Accreditation Appeals Tribunal.

3.8.12 The Accreditation Appeals Tribunal shall consider the notice of appeal and the response of the Service before making an award.

3.8.13 An award of the Accreditation Appeals Tribunal may:

a) Confirm the decision of the service;
b) Vary the decision of the Service;
c) Direct the Service to carry out a fresh evaluation of the application or undertake a fresh assessment of the conformity assessment body; or
d) issue other orders it may consider necessary including an order as to costs.

3.9 Scope Extension

3.9.1 The assessment by KENAS in case of an application for an additional technical area the following assessment methods will be deployed:

a) A review of documents and records;
b) A visit to the office of the CB, to verify documents and records and to interview relevant staff;
c) A witnessed audit.

3.9.2 At least the defined requirements for competence in the technical area, records of the qualification process of auditors for that technical area, and a complete certification report in that category will be verified in a scope extension assessment.

3.9.3 Extension assessments: a witnessed audit shall ordinarily be performed in each technical area for or the applied scope

3.10 General remarks on witnessing

3.10.1 Besides the above-mentioned considerations for selection of audits to be witnessed, KENAS shall consider the following:

3.10.2 KENAS shall ordinarily not witness the same auditors that have been witnessed in the same scheme before;

3.10.3 KENAS shall ordinarily not witness an audit at the same organization;

3.10.4 In an accreditation cycle at least one third (with a minimum of 1) of the audits to be witnessed should be initial or recertification audits.

3.10.5 Witnessing of audits shall include the review of the audit report.

Approved Version

3.10.6 To be able to select the audits to be witnessed, the CB shall on request of the Accreditation Body provide a planning for the audits to be conducted in a certain period. The information on these audits shall include as a minimum:

a) type of audit (initial, recertification or surveillance);
b) name and address of auditee;
c) audit standard(s);
d) scope of certification;
e) name(s) of auditors(s) and expert(s);
f) date(s) of the audit.

3.11 Specific Assessment Issues

3.11.1 During witness assessments, KENAS assessment teams will pay special attention to good auditing practices for medical devices namely, application of risk-based audit planning and prioritize high risk devices & critical processes ((sterilization software validation where applicable). Sampling and the application of audit trails, especially when it comes to the audit of:

a) the internal audit and management review functions;
b) the MDQMS documentation;
c) the recording and evaluation of continual improvement;
d) the organization's systems for achieving statutory and regulatory compliance

3.11.2 During the witness of a stage I audit, special attention will be given to (ref. ISO/IEC 17021-1, cl. 9.2.3.1.1):

a) Planning for stage II;
b) Scope determination;
c) Key elements of the system (e.g. determination of significant aspects);
d) Review of allocation of resources

3.12 Accreditation Standards

For serving national and international demands, KENAS chooses to have the following Standards to serve as the normative standards under the KENAS's MDQMS Certification Accreditation Program:

a) ISO/IEC 17021-1 Conformity assessment – Requirements for bodies providing audit and certification of management systems.
b) ISO 14971
c) ISO 13485
d) IEC 62366-1

Approved Version

4 Associated Documents

A Certification Body (CB) shall satisfy the following normative documents for the accreditation of MDQMS certification activities:

Ref	Document Identifier	Document Title
1.	ISO/IEC 17021-1	Requirements for bodies providing audit and certification of management systems
2.	ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes
3.	ISO 14971	Medical devices — Application of risk management to medical devices
4.	IEC 62366-1	Medical devices Part 1: Application of usability engineering to medical devices
5.	IAF MD 8	Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)
6.	IAF MD 9	Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)
7.	IAF MD 11	Application of ISO/IEC 17021 for audit of Integrated Management Systems

5 Revision/Amendment Records

Date	Ver	Revised By	Reason For Revision
29/06/2026	01	SDE	New document

Approved Version