KENAS
Delivering Trust

KENYA ACCREDITATION SERVICE

ACC-CD-04-01

Criteria for Quality Management Systems

Table of Contents

1 Background Information 2
1.1 Purpose 2
1.2 Scope 2
1.3 Role(s) and Responsibility 2
2 Terms and Definitions 3
2.1 Acronyms and Abbreviations 3
2.2 Definition of Terms 3
3 Criteria 4
3.1 Requirements of Accreditation 4
3.2 Requirements for Application for Accreditation 4
3.3 Determination of Accreditation Scope 5
3.4 Human Resource Requirements 5
3.5 Determination of audit time 6
3.6 On-site Assessment 6
3.7 Witnessing audit plans for initial / reassessment 8
3.8 Selection of witness audits 8
3.9 Maintenance of accreditation 10
3.10 Scope extension 11
3.11 General remarks on witnessing 12
3.12 Accreditation Standards 12
4 Associated Documents 13
5 Revision/ Amendment Record 14
Annex 1: Scopes used for accreditation of QMS certification bodies 15

Approved Version

1 Background Information

1.1 Purpose

This criterion sets out the additional accreditation requirements for Certification Bodies providing certification for the implementation of the Quality Management Systems ISO 9001 and meeting the requirements of ISO/IEC 17021-1 Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements, ISO/IEC 17021-3 Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 3: Competence requirements for auditing and certification of quality management systems, related IAF mandatory documents, related KENAS Policies, procedures and guidance documents.

1.2 Scope

1.2.1 This document spells out the additional requirements to **ISO/IEC 17021-1** and outlines unique Kenyan requirements for third-party certification bodies accredited by KENAS. The criteria in 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 Quality Audits ACC-PR-03-01**, **Policy for Management of Extraordinary Events PL-13-01**, **Policy for dealing with objection of assessors/experts PL-30-01** and the relevant IAF Mandatory Documents. Accreditation shall be on the basis of demonstrated competence of the Certification Body in line with IAF sector codes and the NACE sub codes.

1.2.2 The determination of the scope of accreditation shall be defined as per **IAF ID 1: IAF Informative Document for QMS** and **EMS Scopes for Accreditation** and the lists of scopes of accreditation based on the statistical nomenclature for economic activities **NACE rev. 2** published by the Commission of European Communities (official Journal L 393/1, 30.12.2006.

1.3 Role(s) and Responsibility

Role	Responsibility
Certification Department	Process owner
SCBO	Reviewer
CMIV	Recommender
CEO	Approval
Certification Bodies	Compliance

Approved Version

2 Terms and Definitions

For the purpose of this manual, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the Kenya Accreditation Service Act 2019.

2.1 Acronyms and Abbreviations

AB	Accreditation Body
CEO	Chief Executive Officer
CB	Certification Body
CMIV	Chief Manager, Inspection and Verification
CMLA	Chief Manager, Laboratories
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KENAS	Kenya Accreditation Service
NACE	Statistical classification of economic activities in the European Community
SCBO	Senior Accreditation Officer, Certification
QMS	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.

2.2.2 Scope of accreditation

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

2.2.3 Witnessing

An observation of the CAB carrying out conformity assessment services within its scope of accreditation.

Approved Version

2.2.4 Auditor time

The time spent by an Auditor or Audit Team in planning (including off-site document review, if appropriate); interfacing with organization, personnel, records, documentation and processes; and report writing.

2.2.5 Auditor Day

A full normal working day of 8 hours.

2.2.6 File review

Activity performed by an AB whereby it reviews and evaluates the records and documents pertaining to a given certification file, in order to determine whether the relevant CB procedures were followed and implemented. This is ordinarily done at the CB premises, with the appropriate CB staff and/or auditors, although it may be performed remotely or elsewhere (e.g. CB client premises) as appropriate and agreed.

2.2.7 NACE codes

This is the standard European nomenclature of productive economic activities. They divide the universe of economic activities such that a NACE code can be linked to a statistical unit performing the activity it designates.

3 Criteria

3.1 Requirements of Accreditation

The requirements for management system implemented by the certification body including requirements for management system manual; document and record control; preventive actions, nonconformities and corrective actions; internal audits; management reviews; complaints shall be as outlined in ISO/IEC 17021-1

3.2 Requirements for Application for Accreditation

3.2.1 The following are the additional requirement that a CB applying for accreditation shall provide:

a) Information regarding the CB's general features, including its corporate entity, name, address, legal status,
b) Information regarding its activities, relationship with a larger corporate entity and related bodies,
c) Identification and addresses of all the physical locations to be covered by the scope of accreditation and those locations that carry out key and/or critical activities.
d) Description of the conformity assessment services undertaken, including a list of standards, methods or procedures for which the CB seeks accreditation, including limits of capability where applicable;

Approved Version

e) Clearly defined requested scope of accreditation for the respective management system program and its related technical scope(s) and/or sector scheme programs.

3.2.2 A typical application package includes the following:

a) Application document
b) Corporate Profile
c) Copy of documents demonstrating legal status
d) Organizational charts
e) Survey of Critical locations
f) Matrix identifying where in the CB's system documentation that accreditation requirements are met
g) Management System Documents; including certification program procedures, records and other supporting documentation which demonstrate conformity to the accreditation and/or sector scheme criteria
h) Matrix of auditors/technical experts which identifies their qualifications for the applicable scopes, sector scheme and standards to be issued by the CB.

3.3 Determination of Accreditation Scope

3.3.1 KENAS has adopted the 39 Scope Sectors recognized by IAF as outlined in IAF ID 1 IAF Informative Document for QMS and EMS Scopes for Accreditation and the Scope sectors based on the statistical nomenclature for economic activities NACE rev. 2 published by the Commission of European Communities (official Journal L 393/1, 30.12.2006) classification.

3.4 Human Resource Requirements

3.4.1 The CB would be expected to identify the technical areas for which it seeks accreditation and clearly demonstrate that it has the competence to offer certification in these areas.

3.4.2 The Certification body shall document relevant competence criteria as a basis for selecting auditors and/or technical experts.

3.4.3 The certification body shall ensure that the persons involved in the audit process including review of application to making of certification decisions are competent for the specific scopes.

3.4.4 The documented criteria shall have the required knowledge and skills necessary to effectively perform audit and certification tasks to be fulfilled to achieve the intended results.

Approved Version

3.4.5 The MS certification body shall define the competence requirements for personnel involved in the management and performance of audits and other certification activities. Competence criteria shall be determined with regard to the requirements of each type of management system standard or specification, for each technical area, and for each function in the certification process.

3.4.6 The MS Certification body shall develop competence criteria for QMS personnel as prescribed in **ISO/IEC 17021-3 clause 5.2 to 5.6** and consistent with the requirements specified in **clauses 6.1 to 6.7**.

3.4.7 Certification Body shall define the specific knowledge and skill of its personnel and shall provide competence requirements for each function are stated in **Clauses 4, 5 and 6** of **ISO/IEC 17021-3** as summarized in the table below:

Knowledge	**Certification functions**	
	Reviewing audit reports and making certification decisions	**Auditing and leading the audit team**
Fundamental concepts and quality management principles	6.2	5.2
Context of the organization		5.3
Client products, services, processes and organization		5.4

3.5 Determination of audit time

3.5.1 The MS certification body shall ensure that audit time and audit duration are clearly defined to allow audit objectives to be achieved.

3.5.2 Calculation of man days for audits shall following the principles described in IAF-MD5. For each calculation the rationale shall be recorded.

3.5.3 Audit time shall be determined based on but not limited to the factors enumerated in the IAF MD 5

3.6 On-site Assessment

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

Approved Version

3.6.2 The on-site assessment shall be conducted at the head office and any critical/key locations. The key activities are described in Clause M7.5.7.2, M7.5.7.3 and M7.5.7.4 of IAF/ILAC A5.

3.6.3 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.
b) Assessment of the applicant's auditors – witnessed assessment

3.6.4 During the office assessment the team samples the files of clients and personnel to cover the scope for which accreditation is sought. At least 1 client and 1 auditor file per IAF sector requested shall be reviewed completely, unless more than 10 IAF sectors have been requested, in which case sectors may be omitted in the sample. This is to be determined by the Team Leader, who should apply the following guidelines:

a) Only the non-critical sectors may be omitted
b) Files from each of the technical clusters (see annex 1) shall have been assessed (i.e. the sample should be representative for the scope requested);
c) Sectors, which are included in the program for witnessing, may be excluded;
d) In total, more than 10 certification files shall be assessed.

3.6.5 The application of the IAF-MD documents shall be verified as applicable.

3.6.6 The lead Assessor shall verify the composition, operations and records-of the Impartiality committee (if in place) to demonstrate how they are handling impartiality

3.6.7 The lead assessor 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.

3.6.8 In case the CB has a relation with a consultancy body, KENAS shall verify files of this consultancy body to verify the effectiveness of measures taken to prevent linkage between the two activities.

3.6.9 The Lead assessor shall check how the Certification Body is Managing the of competence of its staff .

Approved Version

3.7 Witnessing audit plans for initial / reassessment

3.7.1 In line with IAF MD17, all the IAF codes (see IAF ID1) have been merged into a series of technical clusters as appropriate for QMS certification (see annex 1). For each of these clusters, critical codes have been identified.

3.7.2 At least two weeks before the witnessing the KENAS team shall be provided with:

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 auditor assignment rationale information (Competence Criteria) (include rationale for allocation of auditor time and auditor selection);
d) CB Audit Plan;
e) Previous Audit report (including notes), required actions and responses from the previous audit activity;
f) The records of the CB's contract review for this organization (including qualification records for the auditors In case a surveillance or recertification audit used);
g) In case a surveillance or recertification audit is witnessed, a copy of the ISO 9001 certificate issued by the CB;
h) The report of the CB's pre-assessment or stage 1 assessment of the organization's QMS (or other latest report) and the audit plan (or the totality of documents, consistent with the requirements of ISO/IEC 17021-1, cl. 9.2.3.2).

3.8 Selection of witness audits

3.8.1 In line with IAF MD17, all the IAF codes (see IAF ID1) have been merged into a series of technical clusters as appropriate for QMS certification (see annex 1). For each of these clusters, critical codes have been identified.

3.8.2 When deciding how many and which audits are to be witnessed, a balanced selection, based on the scopes applied will be made covering the scopes to be accredited. In general, KENAS shall take into account factors such as:

a) the Certification Bodies' overall performance;
b) factors such as process complexity or legislation etc. which influence the ability of the certified organisation to demonstrate its ability to meet the intended outcomes of the Management System;
c) feedback from interested parties including complaints about certified organizations;
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;

Approved Version

g) number of clients within the Certification Bodies' scope of accreditation;
h) confidence in the Certification Bodies' auditor evaluation and approval process; and
i) previous or other office or witnessing assessment results, etc.
j) complaints, customer surveys;
k) interested parties and regulators requests;
l) the technical clusters already assessed;
m) experience from other types of accreditation of the Certification Bodies;
n) previous history of the Certification Bodies' ability to manage its operations;
o) level of controls exercised by a Certification Bodies over its critical activities;
p) specific scheme requirements; and
q) national agreements with clients.

3.8.3 Next to the office audit activities (where all IAF codes shall be sampled), the following witness selection rules apply for the granting and extension of accreditation of QMS certification to guarantee the appropriate coverage of the applicant scope:

3.8.3.1 if a technical cluster has only 1 critical code, KENAS shall perform a witnessing activity in this critical code to grant accreditation for all the IAF codes in that cluster - e.g. cluster Food, with 1 witnessing activity in IAF code 03, KENAS can grant accreditation in the other IAF codes (01 and 30) of that cluster;

3.8.3.2 if a technical cluster has more than 1 critical code, KENAS shall perform at least a witnessing activity in one of the critical codes that are identified with an "or" (on the "Critical code" column); e.g. in cluster Mechanical, with 1 witnessing activity in IAF code 20 or 22, KENAS can grant accreditation in the other IAF codes (17, 18, 19, 20 or 22) of that technical cluster;

3.8.3.3 if it is not possible to perform a witnessing activity in the IAF code/s identified as critical, KENAS can agree with the CB on one of these two options:

a) KENAS can grant accreditation only in the non-critical IAF code/s of the technical cluster for one of which a witnessing activity is performed (e.g. Food cluster - with 1 witnessing activity in IAF code 30, KENAS can grant accreditation for both IAF code 30 and 01), or
b) KENAS can grant accreditation in all the codes of the cluster, performing an office activity in the critical code/s, but under additional conditions:
    i) that the CB has demonstrated its competence on a documental basis in all the codes of the cluster; and
    ii) that the witnessing activity in the critical code/s takes place before any certificate in the critical code/s based on accreditation is issued. However, in such cases, if the result of the witnessing activity is negative, KENAS shall consider reducing the scope of accreditation.

Approved Version

3.8.4 If the CB wants to be accredited only in one or more non-critical IAF codes, a minimum of one witness audit is required in each cluster with non-critical IAF codes.

3.8.5 In the initial accreditation cycle (meaning from 1st surveillance to the 1st reassessment), KENAS shall perform at least one witnessing activity in each technical cluster. 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 technical cluster, during two successive accreditation cycles. This shall be complemented with other assessment activities to guarantee that each technical cluster is assessed at each cycle. KENAS shall justify why the witnessing programme was reduced. Ordinarily, 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.

3.9 Maintenance of accreditation

3.9.1 The implementation of the ISO 9001 certification system shall be verified during maintenance assessment by KENAS.

3.9.2 The files reviewed during the maintenance of accreditation in a four years period (accreditation cycle) shall cover all the clusters mentioned in annex 1 for which the CB is accredited.

3.9.3 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).

3.9.4 For each four (4) year period, the number of witnesses will be determined based on the following factors:

a) for each cluster of sectors included in the scope of the CB; or
b) 1 per √ (number of auditors qualified for EMS certification).

(Whichever gives the higher number, with a maximum of 10)

Approved Version

3.9.5 When the second factor gives the higher number of witness assessments, the witness assessments 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 witness assessments.

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

3.9.7 The application of IAF-MD1 (multisite), IAF-MD3 (ASRP) and IAF-MD4 (CAAT) shall be verified at least once during the accreditation cycle, when applicable.

3.9.8 The functioning of the impartiality committee (or mechanism) of the certification body will be reviewed in-depth at least once during the accreditation cycle.

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

3.9.10 For each accreditation cycle (surveillances and reassessment), the number of witnesses will be determined based on the following factors:

a) 1 for each cluster of sectors included in the scope of the CB; or
b) 1 per √(number of auditors qualified for QMS certification); (whichever gives the higher number, with a maximum of 10).

3.9.11 When the second factor gives the higher number of witness assessments, the witness assessments should also be spread over all clusters. This formula ensures that both a higher diversity in technical areas as well as a higher number of auditors will increase the number of witness assessments.

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

3.10 Scope extension

3.10.1 The assessment by KENAS in case of an application for an additional scope sector consists of one or more of the following assessment methods:

a) A review of documents and records;

Approved Version

b) A visit to the office of the CB, to verify documents and records and to interview relevant staff;
c) A witness assessment.

3.10.2 At least the defined requirements for competence in that sector, records of the qualification process of auditors for that sector, and a complete certification dossier in that sector will be verified in a scope extension assessment.

3.10.3 Extension assessments: a witness shall ordinarily be performed in each critical code for or the applied scope.

3.11 General remarks on witnessing

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

3.11.2 KENAS will ordinarily not witness the same auditors that have been witnessed in the same scheme before;

3.11.3 KENAS will ordinarily not witness an audit at the same organization;

3.11.4 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;

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

3.11.6 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.

3.12 Accreditation Standards

For serving national and international demands, KENAS chooses to have the following Standard to serve as the accreditation standards under the KENAS's QMS Accreditation Program: **ISO/IEC 17021-1** ***Conformity assessment – Requirements for bodies providing audit and certification of management systems*** and **ISO /IEC TS 17021-3** ***Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems***.

Approved Version

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17021	Conformity assessment — Requirements for bodies providing audit and certification of management systems —Part 1:Requirements
2.	ISO/IEC 17021-3	Conformity assessment —Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems
3.	ISO/IEC 17000	Conformity assessment - Vocabulary and general principles
4.	ISO 19011	Guidelines for quality and/or environmental management systems auditing
5.	IAF MD1	IAF Mandatory Document, Certification of Multiple Sites Based on Sampling
6.	IAF MD 2	IAF Mandatory Document, Transfer of Accredited Certification of Management Systems
7.	IAF MD 3	IAF Mandatory Document, Advanced Surveillance and Recertification Procedures (ASRP)
8.	IAF MD 4	IAF Mandatory Document, Use of Computer Assisted Auditing Techniques ("CAAT") for accredited Certification of Management Systems
9.	IAF MD5	IAF Mandatory Document, Duration of QMS and EMS audits (refer to section 4.3)
10.	IAF MD 8:	Application of ISO/IEC 17011: 2004 in the Field of Medical Device Quality Management Systems (ISO 13485)
11.	IAF MD 9:	Application of ISO/IEC 17021 in the Field of Medical Device Quality Management Systems (ISO 13485)
12.	IAF MD 10	IAF Mandatory Document, Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021: 2011

Approved Version

Ref	Document Identifier	Document Title
13.	IAF MD 11	IAF Mandatory Document, Mandatory Document for the application of ISO/IEC 17021 for audits of integrated management systems (IMS) (2013)
14.	IAF MD 12;	Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries.
15.	IAF MD 15:	Collection of Data to Provide Indicators of Management System Certification Bodies' Performance
16.	IAF MD 16:	Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies
17.	IAF MD 17;	Witnessing Activities for the Accreditation of Management System Certification Bodies
18.	IAF ID 1	IAF Informative Document QMS Scopes of Accreditation
19.	IAF ID3;	Management of Extraordinary Events or Circumstances affecting ABs, CABs and Certified Organisations
20.	IAF ID11;	Information on the Transition of Management System Accreditation to ISO/IEC 17021-1:2015 from ISO/IEC 17021:2011

5 Revision/ Amendment Record

Date	Ver	Revised By	Reason for Revision
10/10/2022	01	CER	Newly developed/formatted document

Approved Version

Annex 1: Scopes used for accreditation of QMS certification bodies

Technical cluster	IAF code	Description of economic sector/activity, according to IAF ID1	Critical code(s)
Agriculture, forestry and fishing	1	Agriculture, forestry and fishing	1
Food	3	Food products, beverages and tobacco	3
	30	Hotels and restaurants	
Mechanical	17	Limited to “Fabricated metal products”	20 or 21
	18	Machinery and equipment	
	19	Electrical and optical equipment	
	20	Shipbuilding	
	21	Aerospace	
	22	Other transport equipment	
Paper	7	Limited to “Paper products”	9
	8	Publishing companies	
	9	Printing companies	
Construction	28	Construction	28
	34	Engineering services	
Goods production	4	Textiles and textile products	4 and 5
	5	Leather and leather products	
	6	Wood and wood products	
	23	Manufacturing not elsewhere classified	
Chemicals	7	Limited to “Pulp and paper manufacturing”	7 and 10 and 12 and 13

Approved Version

Technical cluster	IAF code	Description of economic sector/activity, according to IAF ID1	Critical code(s)
	10	Manufacture of coke and refined petroleum products	
	12	Chemicals, chemical products and fibres	
	13	Pharmaceuticals	
	14	Rubber and plastic products	
	15	Non-metallic mineral products	
	16	Concrete, cement, lime, plaster, etc.	
	17	Limited to “Base metals production”	
Mining and quarrying	2	Mining and quarrying	2
Supply	25	Electricity supply	25 or 26
	26	Gas supply	
	27	Water supply	
Transport & Waste management	31	Transport, storage and communication	24 and 39 (limited to NACE 37, 38.1, 38.2, 39)
	24	Recycling	
	39	Other social services	
Services	29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	29 or 35 or 36
	32	Financial intermediation; real estate; renting	
	33	Information technology	
	35	Other services	
	36	Public administration	
	37	Education	
Nuclear	11	Nuclear fuel	11
Health	38	Health and social work	38

Approved Version