KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

ACC-CD-27-01

Criteria for Product Certification Bodies

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1 Background Information

1.1 Purpose

This criterion sets out the additional accreditation requirements for Products Certification Bodies providing product certification in line with **ISO/IEC 17065** Conformity assessment -- Requirements for bodies certifying products, processes and services, scheme specific standards, related IAF mandatory documents, related KENAS policies, procedures and guidance documents.

1.2 Scope

1.2.1 The criteria in this document will be applied in conjunction with those in the Assessor Guide ACC-CD-02-01, the procedure on Management of Assessment, Surveillance, Re-Assessment and Reporting ACC-PR-09-08, Sampling Procedure ACC-PR-03-01, Policy for Management of Extra Ordinary Events PL-12-01, Policy for dealing with Objection of Assessor-Expert PL-30-01 and the relevant IAF Mandatory Documents. Accreditation shall be on the basis of demonstrated competence of the Product Certification Body in line with IAF sector codes and the NACE sub codes.

1.3 Role(s) and Responsibility

Role	Responsibility
All KENAS Technical Staff	Process owner
MEDO	Reviewer
CMLA	Recommender
CEO	Approval
Accreditation Committee	Compliance

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

CEO	Chief Executive Officer
SCBO	Senior Accreditation Officer, Certification
CMIV	Chief Manager, Inspection Verification
KEBS	Kenya Bureau of Standards

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KENAS	Kenya Accreditation Service
NSB	National Standards Body

2.2 Definition of Terms

2.2.1 Accreditation

A 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 Product certification.

Procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements. 'Product' is used here to include product, process or service.

2.2.3 Certification Mark

A protected mark, applied or issued under the rules of a certification scheme, indicating that confidence is provided that the relevant product, process or service is in conformity with specific standards or normative documents

3 Criteria

3.1 Requirements for Product Certification System

The requirements for product certification system implemented by the product 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 17065

3.2 Determination of Scope

KENAS has adopted the 39 sectors scope of economic activities recognized by IAF as outlined in IAF ID 1 IAF Informative Document for QMS and EMS Scopes for Accreditation and the sectors scopes 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.

3.3 Determination of Audit Time

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

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

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

3.4 Critical location

3.4.1 The product certification body shall document location where its critical activities are undertaken in Clause M7.5.7.2, M7.5.7.3 and M7.5.7.4 of **IAF/ILAC A5**.

3.4.2 KENAS shall evaluates and reviews this decision based on specifications set out in **ISO/IEC 17011** (Clause 7.5.7, 7.5.8) and in **IAF/ILAC-A5:07/2012** (Clause M.7.5.7.2).

3.5 Accreditable Product Certification Schemes

3.5.1 The certification bodies shall develop at least one product certification schemes in line with the functional approach as described in **ISO/IEC 17000:2004**, Annex A.

3.5.2 The Elements of product certification systems upon which product evaluation and certification decisions are made, are:

a) Type testing or examination
b) Testing or inspection of samples taken from the market or from the supplier's stock, or both
c) Testing or inspection of every product or of a particular product, whether new or already in use
d) Batch testing or inspection
e) Design appraisal

3.5.3 These product certification schemes shall be supported by:

a) audit and surveillance of supplier's quality system
b) arrangements for licensing the supplier to use certificates or marks
c) arrangements for on-going audit of the products

3.6 Product Type Approval Scheme

3.6.1 This is where a sample of the product type is evaluated. i.e., a supplier submits a sample "typical of the product to be manufactured and the product certification body confirms compliance with the standard or normative document, a type approval certificate is issued by the certification body.

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3.6.2 As there is no audit of the supplier's capability to control manufacture, test/inspect the product, storage, or quality management systems etc., or any on-going product checks then the supplier cannot apply any mark to the product which indicates the marked product complies with the standard.

3.6.3 The supplier can only confirm that a product of the type (purchased say) has been tested (at some time previous) and found to be compliant with the standard.

3.6.4 The certification body does not have any on-going involvement with the supplier or the product once a type approval certificate has been issued, and in fact it is the supplier's responsibility to resubmit the product for re-examination if/when the supplier feels any modifications to the product design or construction significantly changes the validity of the type approval certificate.

3.7 "Full" Product certification Scheme

3.7.1 This involves the same type approval checks (evaluation of the design of the product, inspection, test against the criteria of the standard/normative document), followed by an audit of the suppliers manufacturing controls, quality controls and quality management systems as applicable to the product.

3.7.2 The supplier is awarded certification for the product and is allowed to mark every product with the certification body mark, confirming that the specific product (supplied) does in fact comply with the standard/normative document.

3.7.3 The confidence that the certification body has to allow use of their mark in this way is established via the satisfactory audit of the supplier and **Ongoing Surveillance Visits to the Supplier** along with independent selection and testing/inspection of **Audit Samples**.

3.8 Product Scheme Requirements

3.8.1 The product certification body shall ensure that product certification schemes are based on technically suitable normative documents which define the specification for product conformance and which have been formulated in conjunction with representatives from the relevant industry sector.

3.8.2 The scheme must be designed to be;

a) capable of delivering conforming products consistently (**specification**);
b) capable of being consistently applied by producers to deliver conforming products (**applicability**).
c) capable of being certified consistently (**certifiable**)

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3.8.3 The scheme requirements are normally described in a certification body's scheme document (a product specific manual, or a protocol or similar) and references to any applicable National/International Standards are quoted, similarly legislation requirements would also be identified.

3.8.4 The scheme document shall also contain any additional requirements that the supplier has to satisfy, e.g., qms criteria, (which may be by reference to an **ISO 9001** certified quality system, or only those requirements for manufacturing/quality control and testing as applicable). In addition the product sampling requirements for initial type testing and for audit sampling should be specified.

3.8.5 The scheme document shall contain all the information a supplier would need to know in order to obtain certification of the product.

3.9 Human Resource Requirements

3.9.1 The product certification body shall document the relevant competence criteria as a basis for selecting auditors trained on **ISO 19011** and/or technical experts.

3.9.2 The product certification body shall define the competence requirements for personnel involved in the management and performance of audits and other certification activities. Audit of a client's management system and/or production processes shall be performed by an audit team consisting of a lead auditor and where necessary, auditor(s) and technical expert(s). The Product Certification body may develop a system to train and authorize lead auditors and auditors with reference to Section 7 of **ISO 19011**.

3.9.3 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.

3.9.4 The product 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.

3.9.5 The Product certification body shall implement a system to regularly monitor the performance of its personnel.

3.9.6 The training and authorization of a person for carrying out inspection activities supporting the certification process should cover the following aspects;

a) Requirements of **ISO/IEC 17020** and relevant KENAS guidance documents; and
b) Principle and practice of the production processes for the specified product(s).

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3.9.7 The training and authorization of a person for carrying out or witnessing testing activities at a testing laboratory should cover the following aspects;

a) Requirements of **ISO/IEC 17025** and relevant KENAS guidance documents;
b) Requirements of the applicable product standard(s).

3.9.8 A technical expert who provides technical support to an audit team shall work under the direction and close supervision of a competent lead auditor or auditor. For example, the technical expert should;

a) Have an appropriate knowledge and understanding of the relevant industry;
b) Have adequate knowledge in the design and production of the product to be evaluated;
c) Be familiar with the product standard(s) and applicable regulatory requirements;
d) Have sufficient understanding of the technical aspect of the product certification scheme and be able to effectively evaluate the client's conformity with the product certification scheme.

3.9.9 Certification decision shall be made by a person or a group of persons such as a committee.

3.10 Preliminary requirements

3.10.1 The product certification body shall have granted at least two certifications under the Scheme for which it is seeking accreditation. If accreditation is sought for more than one Scheme, one certification per scheme would be sufficient

3.10.2 The product certification body shall have carried out minimum one internal audit against the applicable criteria of accreditation and one management review.

3.10.3 The product certification body shall have held at least one meeting of the impartiality committee, if specified in the Scheme

3.11 Application

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

3.11.2 Description of the conformity assessment services undertaken, including a list of standards, methods or procedures for which the PC seeks accreditation, including limits of capability where applicable;

a) Certification scheme documentation, including certification criteria
b) Certificate content (example)
c) Validation report of the certification scheme

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d) Cross reference table between accreditation criteria and the documented system
e) Report on recent internal audit, management review
f) Organization structure;
g) Compliance with the program requirements for the proposed certification scheme
h) The following documented procedures;
   i. the normative document specifying the criteria against which the product is certified;
   ii. the documents in which the methods for assessing the conformity of the product are documented;
   iii. the documents in which criteria for competence of the CAB are stated;
   iv. the documents in which requirements related to the procedures for certification, surveillances, recertification, etc. are stated;
   v. the documents in which requirements and procedures for use of marks are stated.

3.12 On site Assessment

3.12.1 The full assessment involves, but is not limited to:

a) Interviews with technical staff;
b) Demonstration of selected certifications including, as applicable, certifications and related activities
c) performed at representative field locations;
d) Assessment of the management system to verify that it is fully operational, conforms to all sections of **ISO/IEC 17065**, and contains all the required documentation;
e) A written report of assessor findings; and

3.13 Evaluation

3.13.1 In case the evaluation is performed through witnessing testing activities at a test laboratory (e.g. a third-party laboratory or a laboratory controlled by the client), the certification body shall have measures to ensure that the laboratory is competent to perform the test, such as a periodic on-site evaluation of the laboratory by the certification body's qualified personnel in accordance with **ISO/IEC 17025** and appropriate test methods/standards.

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3.13.2 Before witnessing the test, the certification body's responsible person should check the technical aspect of the laboratory which may affect the validity of the test results as detailed in **ISO/IEC 17025**. Record of witnessing, which shall include sufficient evidence to assure that the test results are valid, shall be retained by the certification body.

3.13.3 All persons authorized for witnessing testing activities will be assessed by HKAS during an on-site assessment visit. Where necessary, the KENAS assessment team will witness the witnessing of tests carried out by the certification body as part of the KENAS assessment.

3.13.4 For a test conducted by a laboratory accredited to **ISO/IEC 17025** by KENAS or its MRA partner, the competence of the laboratory is considered demonstrated if the test results are presented in an endorsed test report which bears the accreditation symbol of the accredited laboratory.

3.14 Witnessing

3.14.1 Witnessing is generally carried out at the place where the activities in the context of the certification process are executed. Depending on the certification scheme, this may take place at the premises of the product certification body or at other places where activities take place in the context of the evaluation or, if required by the nature of things, in the form of interviews.

3.14.2 The extent of the required witnessing as part of the assessment process shall be determined by the KENAS based on the following principles;

a) The initial accreditation of a certification body shall be covered by at least one witness
b) If the activities of the product certification body can be initiated only after an accreditation was granted, as stipulated by law or similar provisions, there is the option to determine a witness for the first certification carried out under the accreditation and to establish this as a requirement in the official decision on accreditation.

3.14.3 Moreover, the extent of witnessing shall depend on, among other things:

a) The type and number of the certification schemes,
b) The risks posed by the products, processes, and services to be certified,
c) The number of certificates issued,
d) The number of locations where certification activities take place,
e) The number of countries where certificates are issued,
f) The number of auditors used,
g) The staff turnover in the certification body,
h) The feedback from any third party, as well as
i) Special requirements of the scheme owner.

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3.14.4 During an accreditation cycle, the certification activities, certification schemes, and product groups shall be covered by adequate witnessing.

3.15 Certification Documentation

3.15.1 An accredited certification body shall issue a KENAS accredited certificate which bears the KENAS accreditation symbol to its client for a product certified under its accredited product certification scheme provided that the certification body complies with the requirements specified in the agreement on the use of marks.

3.15.2 A KENAS accredited certificate shall only contain the results of certification for which the certification body is holding valid accreditation.

3.15.3 An applicant or accredited certification body shall provide the format of its proposed KENAS accredited certificate the agreement on the use of marks.

3.16 Use of certificates and marks of conformity

3.16.1 The following requirements are additional to those stated in clause 4.1.3 of **ISO/IEC 17065:2012**.

a) The certification body shall ensure that the Certification mark is affixed only to products covered under the scope of the certificate.
b) The product certification body shall ensure that the applicants are not applying the Certification mark on products prior to certification.
c) A certification body shall have procedures to ensure that its marks are not used in a way that may be likely to confuse or mislead the market.
d) The certification body shall have documented procedures to ensure a traceable link from its mark to the relevant certification requirements.
e) The certification body shall have documented procedures for the use of its mark (see also **ISO/IEC 17030**), and for the measures to be adopted in case of misuse, including false claims as to certification and false use of certification body marks and these shall be part of its agreement with the certified clients (FBOs)
f) The Certification Body shall have a documented procedure for dealing with instances of non-compliances with respect to the specified requirements for use and display of KENAS Marks, certificates,
g) In case the Certification Body runs more than one product certification schemes, then it is may have a procedure specifying generic requirements common to all schemes and in line with the requirements of **ISO/IEC 17065:2012**
h) The procedure shall include the process steps and the actions (including penal actions as relevant), the CB intends to take in the event of observing misuse/misleading use of the Mark certificates and marks on the product used for indicating a product is certified, found in documentation or other publicity.

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i) If a certification body incorrectly claims accredited status for certificates issued before
j) appropriate accreditation has been granted, the accreditation body shall require it subsequently
k) to withdraw them and also impose any other sanctions as deemed appropriate.

3.17 Reassessment and Renewal of Accreditation

3.17.1 KENAS shall conduct a full reassessment of all accredited product certification bodies at least every four years.

3.17.2 Reassessments are also conducted when evaluations and submissions from the product certification body or its clients indicate significant technical changes in the capability of the product certification bodies have occurred.

3.18 Adding to the Scope of Accreditation

3.18.1 Unless the previous assessor can verify the competence and capability of the organization to perform the additional certifications, another assessment at the organization's site is normally required.

3.18.2 If the scope expansion request is unrelated to a currently accredited certification scheme, another assessment will be required.

3.18.3 Similarly, if a product certification body relocates, a follow-up assessment is normally warranted.

3.19 Specific Assessment Subjects

3.19.1 For product certification the KENAS assessment team shall especially address the following issues (as applicable):

a) Compliance with applicable standards **ISO/IEC 17021**, **ISO/IEC 17020** and **ISO/IEC 17025** for audits, inspection and/or testing activities being part of the product evaluation activity;
b) Content of the certificate and the statement of conformity issued by the CB;
c) Use of marks;
d) Surveillance activities (also related to the use of marks);
e) The certification scheme is in-line with **ISO/IEC 17067**
f) The organizational requirements of the certification body relating to the development/validation and the introduction of new products and/or product requirements in the certification scheme;
g) The specific procedure of the certification body relating to the development/validation and introduction of new products and/or product requirements in the certification scheme, illustrated by examples;
h) The competence of the staff involved and the presence of the relevant product-related, technical expertise as well as knowledge on how to use

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the same, and knowledge relating to the manufacturing processes of the relevant products (in accordance with Clauses 6.1.2, 6.2, 7.5.1, 7.6.2 of **ISO/IEC 17065**);

i) Performance of the tasks of the top management in accordance with Clause 5.1.3 of **ISO/IEC 17065**;

j) measures necessary for the adaptation of the requirements relating to Clauses 7.4 to 7.7 of **ISO/IEC 17065** as well as corresponding evidence and records.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17030	Conformity assessment - General requirements for third-party marks of conformity
2.	ISO/IEC Guide 7	Guidelines for drafting of standards suitable for use for conformity assessment
3.	ISO/IEC Guide 28	Conformity assessment - Guidance on a third-party certification system for products
4.	ISO/IEC Guide 53	Conformity assessment - Guidance on the use of an organization's quality management system in product certification
5.	ISO/IEC Guide 67	Conformity assessment - Fundamentals of product certification

5 Revision/ Amendment Records

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

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