



MAURITAS A31

MAURITAS -Criteria for Determination of Suitability and Acceptance of Product Certification Schemes for Accreditation Purposes

Mauritius Accreditation Service

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Foreword

The MAURITIUS ACCREDITATION SERVICE (MAURITAS) is a governmental body established in 1998 to provide a national, unified service for the accreditation of Conformity Assessment Bodies (CABs) such as calibration/testing laboratories, certification bodies and inspection bodies. Organizations that comply with the MAURITAS requirements are granted accreditation by MAURITAS.

About MAURITAS publications

MAURITAS publications are categorized as follows:

- R series Publications containing general policy and requirements related to MAURITAS accreditation.
- G series Publications providing guidance on MAURITAS requirements.
- A series Publications related to assessment procedures.
- P series MAURITAS quality system procedures
- F series MAURITAS Forms
- Directories Classified listing of accredited organizations.

Mauritius Accreditation Service (MAURITAS)
4th Floor, Crescent House
Corner Deschartes and Foucault Streets
Port Louis
Mauritius
Tel: +230 208 1690
Fax: +230 210 6101
Email: mauritas@govmu.org
Website: www.mauritas.org

Criteria for Determination of Suitability and Acceptance of Product Certification Schemes for Accreditation Purposes

1. Purpose

1.1 This procedure determines the suitability and acceptance of Certification Schemes for Product Certification Bodies (PCBs).

2 Scope and Responsibilities

2.1 This procedure is applicable to Certification Schemes for product/process/service certification; hereafter termed as product certification. All personnel involved in these activities have the responsibility to adhere to this procedure.

3. References

The following documents contain provisions which, through reference in this text, constitute provisions of the MAURITAS accreditation system. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated MAURITAS references, the latest edition of the document referred to applies. MAURITAS maintains a register, of the current valid MAURITAS accreditation documents.

3.1 **ISO/IEC 17011** : Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

3.2 **ISO/IEC 17065** : Conformity assessment – Requirements for bodies certifying products, processes and services

3.3 **ISO/IEC 17067** : Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes

3.4 **ISO/IEC 17007** : Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment

3.5 **IAF MD 25** : Criteria for evaluation of Conformity Assessment Schemes

4 Definitions

4.1 Product Certification Scheme

Certification system related to specified products, to which the same specified requirements, specific rules and procedures apply

4.2 Certification system

Rules, procedures and management for carrying out certification

4.3 Product Certification system

“Product certification system” is a conformity assessment system that includes selection, determination, review and finally certification as the attestation activity.

4.4 Scheme Owner

Person or organisation responsible for developing and maintaining a specific certification scheme.

Examples of Scheme Owners: Standardization bodies, Conformity Assessment Bodies (CABs), Organizations that use services provided by CABs, Organizations that buy or sell products subject to conformity assessment activities, Manufacturers and their associations that have established their own Conformity Assessment Schemes, Organizations set up specifically for that purpose and Governmental Authorities including regulators and other governmental bodies.

4.5 Certification Body

Third-party conformity assessment body operating certification schemes

4.6 Impartiality

Presence of objectivity

5 Classification of Product Certification Schemes

5.1 The Product Certification Schemes for which the PCBs offer certification may belong to one of the following categories:

Category I

Internationally known Product Certification Schemes which are owned by independent bodies (scheme owners) and are operated at a global level by various PCBs, approved by the scheme owners directly or based on accreditation by Accreditation Bodies recognized by the scheme owners. These schemes are generally developed by the scheme owners in accordance with the principles described for example ISO/IEC 17067 for product / process certification and are operated under their control by approved (generally accredited) PCBs. e.g. GlobalGap Scheme, BRCGS Scheme

Category II

Product Certification Schemes embodied in regulations promulgated under the control of respective governments e.g. Organic Certification scheme.

Category III

Product Certification Schemes developed by governmental department or operated by regulators even if voluntary e.g. Geographical Indicators scheme

Category IV

Product Certification Schemes developed by nongovernmental agencies in fulfillment of their organizational objectives. These could be developed by a group of industries / industry associations, purchasers, distribution / retail chains, consumers / consumer associations, trade associations etc.

Category V

Product Certification Schemes which are developed and operated by CBs themselves e.g. MAURICERT scheme.

6 Criteria for acceptance of Product Certification Schemes

6.1 Product Certification Schemes belonging to any of the types/categories as specified above are acceptable provided they meet the generic criteria/requirements as specified in this document and their suitability is established. However, in case of schemes belonging to categories specified in Category I and Category II, exceptions may be accepted at the discretion of the Director of MAURITAS. The reasons for permitting such exceptions/deviations are:

- a) In case of **Category I**, the scheme owner would be an independent body which takes responsibility for validation of the scheme; the scheme should have been in the market for some time (1 – 2 years) with evidence of its acceptance by the relevant stakeholders, which would be deemed to have automatically

validated the scheme. In case of new schemes, if all the requirements of this document are met with, then the same may be accepted even without having been in the market. However, the scheme will be subjected to a review by MAURITAS after 2 years of their acceptance.

- b) In case of **Category II**, the government/ regulator being the scheme owner takes responsibility on behalf of the stakeholders. It should not prevent MAURITAS from advising the government/regulator on the desirability of aligning the scheme with the policy and criteria laid out in this document which is based on international norms.

In all other cases, the schemes would be required to meet the criteria laid down in ‘Types/Categories of Product Certification Schemes’ of this document.

- 6.2** The evaluation for determination of suitability of Product Certification Scheme shall be done by MAURITAS at the time of application for accreditation for a specific scheme for the first time, **F5.01**. Once a specific scheme has been evaluated and accepted by MAURITAS, the same shall not be re-evaluated in case any other PCB applies for accreditation for the same scheme. MAURITAS may decide to re-evaluate the scheme, when any major changes occur in the contents of the scheme.

7 Requirements and criteria for evaluation of suitability of the Product Certification Schemes

7.1 General Requirements

- 7.1.1** The decision to develop a Product Certification Scheme should be based on several factors including:

- a) the societal or economic need or demand for assurance that can be satisfied by a demonstration that the product meets specified requirements;
- b) the balance between the potential advantages and the potential disadvantages (e.g. adding costs, distorting market access and creating unnecessary technical barriers to trade);
- c) the impact of the proposed Product Certification Scheme on affected parties;
- d) the bodies that would be most effective and efficient to perform product certification and their availability;
- e) existing of Product Certification Schemes and regulations that could fulfil the societal or economic need or demand, or could serve as a model for a new Product Certification Scheme;
- f) the existence of fully developed international, regional, national normative documents;
- g) the availability of an entity assuming scheme owner’s responsibilities.

- 7.1.2** The Product Certification Scheme shall have been developed and maintained by a scheme owner having responsibility for the Certification Scheme and fulfilling the following requirements:

- a) The scheme owner shall be a legal entity. A governmental scheme owner is deemed to be a legal entity on the basis of its governmental status. In cases where the PCBs themselves are the scheme owners, the legal status of the scheme owners shall be that of the certification bodies themselves. In respect of other type of scheme owners, the legal entity status shall be established and demonstrated.
- b) The scheme owner shall have financial stability and resources required to run the Product Certification Scheme and shall be able to take on full responsibility for the objectives, the content and the integrity, validity and robustness of the scheme. During the development of the scheme, the scheme owner should evaluate and manage the risks/liabilities arising from implementation of the scheme and provide appropriate safeguards in such a way that the objectives of relevant

Product Certification Scheme be met. The scheme owner may prescribe minimum requirements to cover liabilities arising from operating the Product Certification Scheme (e.g. insurance or reserves).

7.2 Development of Product Certification Schemes

- 7.2.1** The scheme owner should set up an institutional structure for the development, operation and management of the scheme. The scheme owner shall ensure that the scheme is developed by persons competent in both technical and conformity assessment aspects. In cases where the PCB itself is the scheme owner, the structure may be created within the legal entity, which is preferably independent from the structure involved in operation of the product certification. All the requirements applicable to the scheme owner as described in this document then will be applicable to this structure within the PCB.
- 7.2.2** To ensure that the scheme owner understands the assumptions, influences and consequences involved in establishing, operating and maintaining a scheme on an ongoing basis, the scheme owner shall identify stakeholders and seek their opinions and participation in development of the scheme keeping balance of interest in view.
- 7.2.3** The scheme owner shall document the content and description of the scheme. The description shall be detailed enough to enable the PCBs to implement the same in an unambiguous and consistent manner. The scheme owner shall maintain the scheme, provide guidance when required and make arrangements to protect the confidentiality of information provided by the parties involved in the scheme. The scheme description and documents, including the criteria and process to be used in assessing conformity, shall be publicly available to all stakeholders on its website.

7.3 Operation and maintenance of the Product Certification Scheme

- 7.3.1** The scheme owner shall ensure that the scheme is regularly reviewed, including confirmation that it is fulfilling its objectives, in accordance with a process that includes participation of the stakeholders.
- 7.3.2** The scheme owner shall define a process for reviewing the operation of the scheme on a periodic basis in order to confirm its validity and to identify aspects requiring improvement, taking into account feedback from stakeholders. The review shall include provisions for ensuring that the scheme requirements are being applied in a consistent manner.
- 7.3.3** The scheme owner shall monitor the development of the standards and other normative documents which define the specified requirements used in the scheme. Where changes in these documents occur, the scheme owner shall have a process for making the necessary changes in the scheme, and for managing the implementation of the changes (e.g. transition period) by the PCBs, clients and, where necessary, other stakeholders. The scheme owner should define a process for managing the implementation of other changes to the rules, procedures and management of the scheme.
- 7.3.4** In order to confirm that the Product Certification Scheme has market/stakeholder acceptance, the scheme should have been in existence for 1 – 2 years.
- 7.3.5** Where sampling is required, the Product Certification Scheme should define when is the sampling carried out and who is permitted to undertake it. Where applicable, the scheme should define the extent to which sampling of the product is required and on what basis such sampling is undertaken.

7.4 Requirements with respect to contents of the Product Certification Schemes

- 7.4.1** The Product Certification Scheme shall specify as a minimum the general aspects such as the scope of the scheme, including the description of the type of product.
- 7.4.2** The requirements against which the product is evaluated are those contained in a standard or other normative documents. These requirements could be established by the scheme owner as part of establishing the Product Certification Scheme. In such circumstances, the principles and guidance given in clauses 4 and 5 of the document ISO/IEC 17007 should be followed.
- 7.4.3** Scheme Owners of Product Certification Scheme should follow the functional approach to conformity assessment, which provides a framework of basic conformity assessment functions and their relationships. The functional approach identifies the following:
- a)** Selection of the product(s), including selecting specified requirements to be assessed and planning information collection and sampling activities;
 - b)** Determination, including the use of one or more determination methods (e.g. test, audit and/or examination) to develop complete information regarding fulfillment of the specified requirements by the product(s) or its sample;
 - c)** Review, Decision and Attestation, including the decision taken further to the review of evidence from the determination stage, and a subsequent attestation that the product has been reliably demonstrated to fulfil the specified requirements, and any subsequent marking or licensing and their related controls; and
 - d) Surveillance (where needed),** including the frequency and extent of surveillance activities and reassessments to ensure the product continues to fulfil the specified requirements. The need for surveillance will depend upon the type of scheme listed in section 'Types/Categories of Product Certification Scheme' of the document ISO/IEC 17067 and whether the claim for continued compliance is permitted by the client over the validity period of the certification.
- 7.4.4** The requirements for Scheme Owners or PCBs involved in the Product Certification, shall not be in contradiction to the requirements of the applicable standard. They may be additional or stricter than those specified in the relevant standards.
- 7.4.5** The methods and procedure, criteria for evaluation as well as reporting requirements shall be decided by the Scheme Owner and ensured that the same are followed by the PCBs engaged for the same, for ensuring integrity and consistency of the outcome of the process of conformity assessment. The Scheme Owner should make use of the provisions described in ISO/IEC 17067 for elaborating the same. Additional guidance / requirements with respect to time required for evaluation tasks, transfer of certificates, multisite considerations and impartiality requirements for PCBs shall be described, as applicable.
- 7.4.6** The conditions under which the client may use the statement of conformity or marks of conformity should be specified as applicable. Where marks of conformity may be used, ownership, use and control of the marks, etc should be specified.
- 7.4.7** The Product Certification Scheme shall describe, as applicable, other generic requirements such as:
- a)** information to be supplied to PCB by the applicant to certification,
 - b)** contents of statement of conformity
 - c)** resource competence requirements in line with the requirements of ISO/IEC 17065,
 - d)** sampling procedures,
 - e)** acceptance of conformity assessment results from other parties,
 - f)** outsourcing of product certification activities,
 - g)** reporting and use of results of determination and surveillance stages by the PCB and the Scheme Owner,
 - h)** how nonconformities with the certification requirements are to be dealt with and resolved for the purpose of decision making,

- i) surveillance procedures, as applicable,
- j) information about certified clients to be made available to public,
- k) general conditions for granting, maintaining, continuing, extending the scope of, reducing the scope of, suspending and withdrawing certification (this should include requirements for discontinuation of advertising and return of certification documents if the certification is withdrawn),
- l) content of contracts between Scheme Owner and PCB, Scheme Owner and clients, PCB and clients, including the rights, responsibilities and liabilities of the various parties,
- m) licensing and control of marks,
- n) complaint handling system to be maintained by the PCB,
- o) reporting to the Scheme Owners,
- p) complaints and appeals to Scheme Owners and
- q) fraudulent claim of certification.

8 Evaluation of schemes

The generic requirements/criteria given in this document are evaluated using the scheme review checklist, **F 5.08**. In addition, specific criteria for product certification are evaluated using specific checklists, **F 5.02** and **F 5.03**.

9 Related Forms

- Application for Accreditation of Product Certification Bodies, **F 5.01**,
- Cross reference matrix cum document review report for management requirements, **F 5.02**
- Cross reference matrix cum document review report for technical requirements, **F 5.03**
- Scheme Review Checklist – Product Certification, **F 5.08**

Appendix A: Amendment Table

SN	Section	Amendment