



DEPARTMENT OF STANDARDS MALAYSIA SCHEME FOR THE ACCREDITATION OF CERTIFICATION BODIES (The ACB Scheme)

ACB 4

Issue 4, 8 October 2019

POLICY ON SCOPE OF ACCREDITATION AND MANAGEMENT OF ACCREDITED SCOPES BY CERTIFICATION BODIES

Authority to Issue

Director General Department of Standards Malaysia

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1. INTRODUCTION

- 1.1 This document details Standards Malaysia policy for the purpose of determining, granting, extending, renewal, reducing, maintaining, reinstating, suspending and withdrawal of scope of accreditation as well as witnessing activities based on the scope of accreditation.
- 1.2 The policy is also applicable for the management of Standards Malaysia accredited scopes by certification bodies for the purpose of determining certification, as well as to determine the resources and competencies to be applied to the audit of an organisation.

2. SCOPE

2.1 The policy applies to all certification bodies applying for Standards Malaysia accreditation and those who are already accredited by Standards Malaysia under the Scheme for the Accreditation of Certification Bodies (ACB Scheme).

3. REFERENCES

- 3.1 ISO/IEC 17011 Conformity assessment Requirements for accreditation bodies accrediting conformity assessment bodies
- 3.2 ISO/TS 22003 Food safety management systems Requirements for bodies providing audit and certification of food safety management systems
- 3.3 ISO 50003 Energy management systems Requirements for bodies providing audit and certification of energy management systems
- 3.4 IAF MD 8 Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485)
- 3.5 IAF MD 16 Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies
- 3.6 IAF MD 17 Witnessing Activities for the Accreditation of Management Systems Certification Bodies
- 3.7 IAF MD 22 Application of ISO/IEC 17021-1 for the certification of occupational health and safety management systems (OH&SMS)
- 3.8 IAF ID 1 IAF Informative Document for QMS and EMS Scopes of Accreditation
- 3.9 ACB GMP General requirements for bodies operating assessment and certification of GMP systems

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- 3.10 ACB-HACCP Standards Malaysia requirements for the accreditation of bodies operating certification of HACCP Systems
- 3.11 ACB-OPMC 1 Competency requirements for certification bodies operating oil palm management certification under the Malaysian Sustainable Palm Oil (MSPO) certification scheme
- 3.12 ACB-SC1/2018 Requirements for certification bodies operating supply chain certification under the Malaysian Sustainable Palm Oil (MSPO) Certification Scheme

4. **DEFINITIONS**

4.1 For the purpose of this document, in addition to the definitions in the relevant ISO standards and IAF documents, the following definitions apply:

4.1.1 ACB Accreditation Criteria

ACB Accreditation Criteria is defined as criteria documents developed by Standards Malaysia for specific accreditation programmes under the ACB Scheme.

4.1.2 **Dormant Scope**

Dormant scope /area is defined as the scope /area where the certification body has qualified auditors / technical experts but does not have any certified organisation.

5. POLICY ON SCOPE OF ACCREDITATION

5.1 Granting of Scope of Accreditation

- 5.1.1 Unless otherwise specified, the scope of accreditation of a certification body is expressed in terms of one or more elements from industrial sectors or product categories, known as the "scope of accreditation" as in ANNEX 1. Standards Malaysia has adopted the statistical nomenclature for economic activities (NACE Rev.2) 2006, published by the Commission of European Communities (official Journal 393/1, 30.12.2006) as the basis for defining the scope of accreditation and certification.
- 5.1.2 Accreditation scope under Standards Malaysia accreditation system is to be defined based on the general scope number. There is no limitation placed on the sub-divisions of the broad description given in Annex 1 that a certification body may seek accreditation for. However, for certification bodies operating in a limited area, such as industry sector-specific certification schemes, the accreditation scope would normally be limited to one broad description as described in ANNEX 1. In some cases, it may be appropriate for the certification body to define its scope at the division, group or class level. In determining the most appropriate scope to apply for, certification bodies may consult Standards Malaysia prior to applying for accreditation.

- 5.1.3 The table listing accreditation programmes whereby the scope of accreditation are specified are as per Annex 2
- 5.1.4 Certification bodies shall document and be able to demonstrate competence to the accreditation programme in order for Standards Malaysia to grant accreditation to the applied scope.

5.2 Dormant scope(s)

- 5.2.1 Standards Malaysia may grant accreditation for dormant scope(s).
- 5.2.2 If the certification body intends to certify in scopes identified as dormant scopes especially identified as critical code(s) the certification body shall submit documentation of its competency as well as allow Standards Malaysia to perform a witness audit prior to activation of dormant scope.
- 5.2.3 However, if after an accreditation cycle (Five (5) years), the Certification Body fails to activate the scope, Standards Malaysia reserves the right to reduce the scope of accreditation.

5.3 Extension of scope(s)

- 5.3.1 If a certification body intends to extend its scope of accreditation, the certification body shall submit documentation of its competency as well as allow Standards Malaysia to perform a witness audit for that particular scope to be considered for granting of extension of scope.
- 5.3.2 If extension of scope is granted for a dormant scope, the activation of a dormant scope shall follow Clause 5.2 of this document.

5.4 Scope of accreditation to a sub-element of a general scope:

- 5.4.1 A certification body can request for a scope to be specified to a specific NACE division, group or class.
- 5.4.2 Standards Malaysia reserves the rights to limit the scope of accreditation to a specific NACE division, group or class.

5.5 Certification Scope

- 5.5.1 Certification bodies shall ensure that at least one member of an audit team should have experience in the scope concerned. Experience in the scope concerned shall be judged using the following guidance:
 - (a) identification of scope of industrial or service sector in which certification is offered; and
 - (b) relevant experience and competence to be within the defined area / sector.

- 5.5.2 The scope of certification shall be defined to be precise and clear so that clients interested parties and the organizations themselves will know accurately and unambiguously the certification scope. In some cases, additional descriptors may be necessary to more closely define the scope of certification. In defining the scope of certification, some attempt should be made to limit the additional descriptors to common terms, so that a uniform description may be applied to all suppliers from that specific industry.
- 5.5.3 For management systems certification, Standards Malaysia will only allow certification bodies to issue Standards Malaysia accredited certificates which include the core business of the organisation being certified.

6.0 POLICY ON WITNESSING ACTIVITIES OF CERTIFICATION BODIES

- 6.1 The scope and witnessing activities will be directly referred whereby they have already been defined in a standard/document for the accreditation programmes listed in Annex 2 of this document.
- 6.2 For Product Certification (PC) Accreditation Programme:
 - 1. Applicants
 - The CB shall be able to demonstrate that it has clients or has auditors who are competent to certify to the scope applied; and
 - ii. Standards Malaysia shall witness at least ONE (1) compliance or ONE (1) recertification or TWO (2) surveillance audits.
 - 2. For extension of scope(s)
 - i. During the office assessment, the assessment team shall conduct file reviews and recommend to Standards Malaysia appropriate scopes to be witnessed.
 - ii. The assessment team may recommend for granting of extension of scope without witnessing.

3. For maintenance of accreditation

Witnessing audits shall be carried out per organization per programme as per the table below:

Certificates Issued per program	1-100	101 - 300	301 - 600	601-1000	>1000*
Annual number of witnessed audits per program, minimum	1	2	3	4	5

*Note: For every subsequent addition of 1,000 organisation, an additional witness audit shall be added.

Table 1 - Annual number of witnessing audits for product CBs

6.3 For Certification of Persons (Persons) Accreditation Programme:

1. Applicants

- The CB shall be able to demonstrate that it has clients or examiners who are competent to certify to the scope applied; and
- ii. Standards Malaysia shall witness examiners conducting assessment on persons based on the certification scheme applied.

2. For extension of scope(s)

- The CB shall arrange a witnessing audit for the certification scheme applied and submit competency records or evidence of relevant personnel; and
- ii. Submission of records or evidence can be submitted prior to witnessing audit or during the audit itself.

3. For maintenance of accreditation

Witnessing audits shall be carried out per accredited certification scheme

6.4 For accreditation programmes besides those mentioned in Table 5.1.3:

1. Applicants

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- The CB shall be able to demonstrate that it has clients or has auditors who are competent to certify to the scope applied; and
- ii. Standards Malaysia shall witness at least ONE (1) compliance or ONE (1) recertification or TWO (2) surveillance audits.

2. For extension of scope(s)

- i. The CB shall arrange a witnessing audit for the code applied and submit competency records or evidence of relevant personnel; and
- ii. Submission of records or evidence can be submitted prior to witnessing audit or during the audit itself.

3. For maintenance of accreditation

Witnessing audits shall be carried out as per the table below:

Certificates Issued per program	1-100	101 - 300	301 - 600	601-1000	>1000*
Annual number of witnessed audits per program, minimum	1	2	3	4	5

*Note: For every subsequent addition of 1,000 certificates, an additional witness audit shall be added.

Table 2 – Annual number of witnessing audits for management systems CBs other than specified above

4. For dormant scope(s)

During re-assessment of the previous cycle, if the CB fails to show evidence of a scope being active, Standards Malaysia shall withdraw the scope from the CB.

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ANNEX 1 STANDARDS MALAYSIA GUIDELINES ON SCOPES OF ACCREDITATION

<u>No</u>	<u>Description</u>	NACE-Division/ Group/
1	Agriculture forestry and fishing	Class (rev.2)
1	Agriculture, forestry and fishing	01, 02, 03
2	Mining and quarrying	05, 06, 07, 08, 09
3	Food products, beverages and tobacco	10, 11, 12
4	Textiles and textile products	13, 14
5	Leather and leather products	15
6	Wood and wood products	16
7	Pulp, paper and paper products	17
8	Publishing companies	58.1, 59.2
9	Printing companies	18
10	Manufacture of coke and refined petroleum products	19
11	Nuclear fuel	24.26
12	Chemicals, chemical products and fibres	20
13	Pharmaceuticals	21
14	Rubber and plastic products	22
15	Non-metallic mineral products	23 except 23.5 and 23.6
16	Concrete, cement, lime, plaster etc.	23.5, 23.6
17	Basic metals and fabricated metal products	24 except 24.46, 25
	·	except 25.4, 33.11
18	Machinery and equipment	25.4, 28, 30.4, 33.12, 33.2
19	Electrical and optical equipment	26, 27, 33.13, 33.14, 95.1
20	Shipbuilding	30.1, 33.15
21	Aerospace	30.3, 33.16
22	Other transport equipment	29, 30.2, 30.9, 33.17
23	Manufacturing not elsewhere classified	31, 32, 33.19
24	Recycling	38.3
25	Electricity supply	35.1
26	Gas supply	35.2
27	Water supply	35.3, 36
28	Construction	41, 42, 43
29	Wholesale and retail trade;	71, 72, 70
29	Repair of motor vehicles, motorcycles and	
	personal and household goods	45, 46, 47, 95.2
30	Hotels and restaurants	
		55, 56 40, 50, 51, 53, 53, 64
31	Transport, storage and communication	49, 50, 51, 52, 53, 61
32	Financial intermediation; real estate; renting	64, 65, 66, 68, 77
33	Information technology	58.2, 62, 63.1
34	Engineering services	71, 72, 74 except 74.2 and
~ =		74.3
35	Other services	69, 70, 73, 74.2, 74.3, 78,
		80, 81, 82
36	Public administration	84
37	Education	85
38	Health and social work	75, 86, 87, 88
39	Other social services	37, 38.1, 38.2, 39, 59.1,
		60, 63.9, 79, 90, 91, 92, 93,
		94, 96

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ANNEX 2 ACCREDITATION PROGRAMMES WHEREBY THE SCOPE OF ACCREDITATION HAVE BEEN SPECIFIED IN NORMATIVE DOCUMENTS

NO.	ACCREDITATION PROGRAMME	REFERENCE DOCUMENT
1.	Food Safety Management Systems (FSMS)	ISO/TS 22003
2.	Energy Management Systems (EnMS)	ISO 50003
3.	Medical Device Management Systems (MDQMS)	IAF MD 8
4.	Quality Management Systems (QMS)	IAF MD 17
5.	Environmental Management Systems (EMS)	IAF MD 17
6.	Occupational Safety and Health Management Systems (OSH)	IAF MD 22 (To be replaced with IAF MD 17 after 20 May 2020)
7.	Good Manufacturing Practices for Food (GMP)	ACB-GMP
8.	HACCP Systems (HACCP)	ACB-HACCP
9.	Malaysian Sustainable Palm Oil Certification Scheme (MSPO)	ACB-OPMC 1

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