ACB-HACCP
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STANDARDS MALAYSIA REQUIREMENTS FOR THE ACCREDITATION OF BODIES OPERATING CERTIFICATION OF HACCP SYSTEMS TO MS 1480

Authority To Issue

Director General
Department of Standards Malaysia

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SECTION 0: INTRODUCTION

0.1   Background

World-wide there have been substantial efforts to develop a reliable and methodical approach to food safety assurance, mostly now based on the Hazard Analysis and Critical Control Point (HACCP) system. HACCP is a systematic, food safety management tool designed to evaluate and control hazards so that specific food safety outcomes can be achieved.

HACCP is not a stand alone system. It depends on management commitment and a solid foundation of prerequisite programs such as Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP) and other relevant Codes of Practice. HACCP is not intended to replace these programmes, nor to diminish their significance. For HACCP to be effective, these prerequisite programmes shall be in place.

Before considering a safety management system such a HACCP, it is advisable to determine if a particular industry segment is ready to build upon existing programmes, or whether attention shall first be focused on basic hygienic practices.

MS ISO/IEC 17021 : Conformity assessment – Requirements for bodies providing audit and certification of management systems, is an International Standard that specifies requirements for certification bodies.

This document, ACB-HACCP which was developed by the technical working group (TWG) provides interpretations to the applications of MS ISO/IEC 17021 in HACCP systems. The term "shall" is used throughout this document to indicate those provisions which, reflecting the requirements of MS ISO/IEC 17021 are mandatory. The term "should" is used to indicate guidance which, although not mandatory, is provided as a recognised means of meeting the requirements. Certification bodies whose systems do not follow these requirements in any respect will only be eligible for accreditation if they can demonstrate to the Department of Standards Malaysia (STANDARDS MALAYSIA) that their solutions meet the relevant clause of MS ISO/IEC 17021 in an equivalent way.

0.2   Field of application

This document sets down the requirements for certification bodies seeking accreditation by STANDARDS MALAYSIA to certify HACCP systems. It is important to understand that these are the requirements that have to be met by certification bodies. They are not requirements that have to be met by the organisation that are audited by the certification bodies. The requirements that must be met by the organisation can be found in the appropriate certification standard.

Accreditation in compliance with these requirements acknowledges that certification bodies possess the necessary competence and reliability to operate a conformity certification scheme and will thereby facilitate the acceptance by regulatory authorities of certificates that they issue.

Accredited certification bodies must appreciate that where their scope of accreditation refers, either directly or indirectly, to requirements laid down by a regulatory authority, the requirements of that regulatory authority, as amended from time to time, may be applied by STANDARDS MALAYSIA in addition to the requirements laid down in this document.

SECTION 1: GENERAL

1.1   Scope

Where MS ISO/IEC 17021 refers to management systems it shall be read as a reference to HACCP systems. The certification standard to be used shall be MS 1480. The scope of certification shall be applicable to any organization in demonstrating conformity to the requirements for food safety according to HACCP system to ensure the safety of food during preparation, processing, manufacturing, packaging, storage, transportation, distribution, handling or offering for sale or supply in any sector of the food chain. Scopes for accreditation are as in Annex 1.

1.2   References

1.2.1. The following references apply:

MS ISO/IEC 17021 - Conformity assessment – Requirements for bodies providing audit and certification of management systems

ISO 9001 – Quality Management Systems – Requirements

ISO 19011 – Guidelines for Auditing Management Systems

MS 1480 – Food Safety According to Hazard Analysis and Critical Control Point (HACCP) System

MS 1514 – Good Manufacturing Practice (GMP) for Food.

IAF MD 2 – IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

CAC/RCP 1-1969 Rev. 4 – 2003 Recommended International Code of Practice, General Principles of Food Hygiene

ISO/TS 22003 – Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems

ISO 22000 - Food safety management systems – Requirements for any organization in the food chain

Food Act 1983 & Food Regulations 1985

Food Hygiene Regulations 2009

NOTE: For undated references,the latest edition of the referenced document (including any amendments) applies.

1.3 Definitions

1.3.1. The following definitions apply:

Critical Control Point (CCP)	:	Critical Control Point (CCP) shall mean a point, operational step or stage in the food chain at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
Food	:	Food includes every article manufactured, sold or represented for use as food or drink for human consumption or which enters into or is used in the composition, preparation, preservation of any food or drink and includes confectionery, chewing substances and any ingredient of such food, drink, confectionery or chewing substances.
Food chain	:	Sequence of the stages and operations involved in preparation, processing, production, preservation, packaging, storage, transportation, distribution, handling or offering for sale or supply of a food and its ingredients, from primary production to consumption.
Food safety	:	Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
HACCP Plan	:	A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.
HACCP system	:	A system consisting of the seven principles which identifies, evaluates, and controls hazard(s) which are significant for food safety.

Nonconformity	:	The absence of, or the failure to implement and maintain, one or more required system elements, or situation which would, on the basis of available objective evidence or evaluation, raise doubt as to the safety of food.
Pre-requisite programs (PRPs)	:	Universal steps or procedures that control the operational conditions within an organisation allowing for environmental conditions that are favourable to the production of safe food. It also includes GMP as in MS 1514.
Validation	:	Obtaining evidence that the elements of the HACCP plan are effective.
Verification	:	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP Plan.

1.4 Accredited Scope

1.4.1   The accredited scope of a certification body is expressed in terms of food chain categories and specific sectors within the categories in which the requirements for a HACCP system are expressed.

1.5 Consultancy

1.5.1   The term "management system consultancy" (as in MS ISO/IEC 17021) in this HACCP system progamme can be referred to "hazard analysis consultancy, food safety system consultancy or any management system consultancy related to food safety and food hygiene".

SECTION 2: REQUIREMENTS FOR CERTIFICATION BODIES

2.1 Application Stage

The certification body shall require the applicant organisation to provide detailed information concerning PRP, description of products, process flow, HACCP plans, number of CCPs, number of effective employees, number of shifts and location.

2.2 Stage 1 Audit

The objective of the stage 1 audit is to provide a focus for planning the stage 2 audit by gaining an understanding of the food safety systems in the context of the organization's infrastructure, food safety hazard identification, hazard analysis, HACCP plan and PRPs, policy and objectives, and, in particular, the organisation's state of preparedness for audit by reviewing the extent to which:

a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory and statutory requirements);

b) the food safety system includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations);

c) food safety legislation is in place for the relevant sector(s) of the organization;

d) the food safety system is designed to achieve the organization's food safety policy and objectives;

e) the food safety (including PRP) system implementation programme justifies proceeding to the audit (stage 2);

f) the HACCP plan has been validated;

g) The HACCP system has been verified;

h) the food safety system documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties, and additional documentation needs to be reviewed and/or other knowledge needs to be obtained in advance before Stage 2.

2.3 Stage 2 Audit

2.3.1   The stage 2 audit shall take place at the site(s) of the organisation. It shall include the review and verification of at least the following:

a) information and evidence about conformity to all requirements of the MS 1480 standard;

b) key food safety objectives and targets (consistent with the expectations in MS 1480 standard);

c) the organisation's HACCP systems and performance as regards legal compliance and PRP;

d) operational control including CCPs during processing of the food;

e) internal audit and management review;

f) management responsibility (including HACCP team) for the organisation's food safety policies;

g) links between the MS 1480 requirement, food safety policy, key food safety objectives and targets (consistent with the expectations in the MS 1480 standard), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

Note: Any part of the food safety system that is audited during the stage 1 audit and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit. However, the certification body shall ensure that the already audited parts of the food safety system continue to conform to the certification requirements. In this case, the stage 2 audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

2.3.2   The interval between stage 1 and stage 2 audits is reasonably expected to be not longer than 6 months. The stage 1 audit should be repeated if :

    1) a longer interval is needed or
    2) there are other conditions or changes which have an impact on food hygiene and food safety

2.4   Surveillance Audit

2.4.1   The certification body shall develop its surveillance activities so that representative areas and functions covered by the scope of the system are monitored and maintained on a regular basis, and take into account changes to its certified organisations and its system and includes focus on the operational control including CCPs during processing of food, critical areas related to significant impact on food safety and food hygiene.

2.4.2   Surveillance audit shall also include a review of:

a) nonconformities from previous audits;

b) changes in raw materials, ingredients, packaging materials, suppliers, products and/or services;

c) changes in production systems and/or equipment;

d) changes in PRPs;

e) changes in personnel, their qualification level and/or allocation of responsibilities;

f) training;

h) anticipated changes of consumer usage and consumer groups;

i) relevant enquiries from external interested parties and/or complaints indicating health hazards associated with the product;

j) changes in regulatory requirements;

k) customer, sector and other requirements which the establishment have undertaken to observe;
l) new knowledge on hazards;

m) verification activities; and

n) other conditions or changes which have an impact on food safety and food hygiene.

2.4.3   The conditions for granting, maintaining, extending, reducing, suspending or withdrawal of certification shall incorporate or otherwise address any relevant regulatory requirements. Withdrawal of certification relating to food safety shall be communicated to relevant regulators without undue delay.

2.4.4   Where the certification body is obliged by law to provide certain information to a regulatory authority, the client shall be informed.

2.4.5   The report by the audit team shall include references to PRPs used by the organization, HACCP system used, comments on the HACCP team, and other issues relevant to the food safety systems.

2.5 Recertification Audit

2.5.1   The recertification audit shall include an on-site audit that addresses the following:

   a) the effectiveness of the HACCP system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;

   b) demonstrated commitment to maintain the effectiveness and improvement of the HACCP system in order to enhance overall performance;

   c) whether the operation of the certified HACCP system contributes to the achievement of the food safety policy and objectives;

   d) the effectiveness of operational control(s) including CCPs during processing of food.

2.5.2   When, during a recertification audit, instances of nonconformity or lack of evidence of conformity are identified, the certification body shall define time limits for correction and corrective actions to be implemented prior to the expiration of certification.

2.5.3   **Information for granting recertification**

The certification body shall make decisions on renewing certification based on the results of the recertification audit, as well as the results of the review of the system over the period of certification and complaints received from users of certification and any other relevant information (e.g : public information, sanction(s) from regulatory authorities)

2.6 Special audits

2.6.1 Extensions of scope

2.6.1.1   The certification body shall respond to an application for extension to the scope of a certification that already granted.

2.6.1.2 The certification body shall undertake a review of the application covering identification of food safety hazard, hazard analysis, HACCP plan and determine any audit activities necessary, to

decide whether or not the extension can be conducted in conjunction with a surveillance audit or separate audit.

2.6.2 Short-notice audits

2.6.2.1 It may be necessary for the certification body to conduct audits of certified clients at short notice to investigate complaints or in response to changes or as follow up on suspended clients. In such cases

a) the certification body shall describe and make known in advance to the certified clients the conditions under which these short notice visits are to be conducted; and

b) the certification body shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

SECTION 3 : CERTIFICATION BODIES' PERSONNEL

3.1 Contract Reviewer

3.1.1 Education

The certification body shall ensure that personnel carrying out contract review have the knowledge corresponding to a post-secondary education.

3.1.2 Food safety training

The certification body shall ensure that personnel carrying out contract review have successfully completed training in:

a) MS 1480;

b) HACCP principles, hazard assessment and hazard analysis; and

c) food safety management principles including pre-requisite programmes (PRPs).

3.1.3 Audit training

The certification body shall ensure that personnel carrying out contract review have successfully completed training in audit processes based on the guidance given in ISO 19011.

NOTE It is not mandatory for personnel carrying out contract review to have or to maintain audit experience.

3.1.4 Competences

The certification body shall ensure that personnel carrying out contract review demonstrate the ability to apply knowledge and skills in the following areas:

a) classification of applicants in food chain categories and sectors/ Category Code;

b) assessment of applicant products, processes and practices;

c) deployment of HACCP system auditor competences and requirements;

d) determination of audit time (see Annex 2) and duration requirements;

e) certification body's policies and procedures related to contract review.

3.2 Auditors

3.2.1   The management of the certification body shall define the requirements for establishing the competence of the auditors and technical experts that the certification body uses to conduct audits, whether they are employees, employed on contract or provided by external bodies. These requirements shall incorporate the relevant criteria for assessing and auditor competence in ISO 19011.

3.2.2   Education

The certification body shall ensure that auditors have the knowledge corresponding to a post-secondary education that includes general microbiology and general chemistry. The certification body shall also ensure that auditors have the knowledge corresponding to a post-secondary education that includes courses in the food chain industry category in which they conduct HACCP audits.

EXAMPLE:

a) For the food industry (Categories C, D, E, G and L in Table 1): food microbiology, food processing fundamentals and food chemistry including food analysis; organoleptic evaluation;. thermal processing for canned and other hermetically sealed foods.

3.2.3   Food safety training

3.2.3.1 The certification body shall ensure that auditors have successfully completed training in:

a)   HACCP principles;
b)   PRPs; and
c)   Regulatory requirement.

The training course shall be conducted by trainer certified by Ministry of Health (MOH).

3.2.3.2 The CB shall also ensure the auditors have been trained on technical operation of specific sectors where required.

3.2.4   Audit training

The certification body shall ensure that auditors have successfully completed training in:

a)   audit techniques based on ISO 19011;

b) HACCP (MS 1480); and
c) GMP standards (i.e., MS 1514 or ISO/TS 22002-1 Prerequisite programmes on food safety – Part 1 : Food manufacturing) and etc.

3.2.5   Work experience

For a first qualification of an auditor in one or more categories, the certification body shall ensure that the auditor has a minimum of five (5) years of full-time work experience in the food-chain-related industry, including at least two (2) years of work in quality assurance or food safety functions within food production or manufacturing, retailing, inspection or enforcement or the equivalent. The number of years of total work experience may be reduced by one year if the auditor has completed appropriate post-secondary education.

3.2.6   Audit experience

For a first qualification, the certification body shall ensure that within the last three (3) years the auditor has performed at least twelve (12) HACCP audit days in at least four (4) organizations under the leadership of a qualified auditor.

For extension to a new category, the certification body shall demonstrate that the auditor has the required competences through relevant education as required in 3.2.2, food-safety-related training in the new category, and either:

- six (6) months of work experience in the new category, or
- four (4) HACCP audits under the supervision of a qualified auditor in the new category.

For extension to new sector within a Category, the CB shall maintain appropriate justification and demonstrate the competence of the auditor.

Note : HACCP plan depends on the products sector or process involved in the manufacturing. For maintaining the qualification of the auditor, the certification body shall ensure that auditors have performed a minimum of five (5) external HACCP audits per year consisting of at least ten (10) audit days.

3.2.7   Knowledge on Regulatory Requirement

The competent personnel shall be aware of current regulatory requirements and food safety issues and there shall be means in place for maintaining that awareness.

3.3   Technical Experts

The certification body shall ensure that technical experts have the knowledge corresponding to a post-secondary education in the food chain industry sector being audited, in the processes being audited or in the food safety hazards applicable to the sector. The certification body shall ensure that technical experts have work experience in their technical area. The certification body shall ensure that technical experts demonstrate the ability to provide expertise in their technical area.

3.4   Audit Team

3.4.1   The audit team needs a background to ensure that the members understand the requirements and have competences in the application of PRPs and HACCP in specific sector they are auditing. Each audit team shall have a general understanding and background in each technological and industrial sector in which it operates. It shall be able to determine whether or not a particular HACCP system adequately complies with the requirements of the HACCP system standard.

3.4.2   The above requires that the audit team, deployed in each case by a certification body to conduct an audit of an organisation's HACCP system, needs to know what elements, general to the processes and procedures, are essential to provide the product in question. An element is essential if failure of a HACCP system to deal with it in a correct manner presents an unacceptable risk that products will not meet specified requirements. The audit team shall have the necessary competence, including sector or regulatory credentials, to determine whether the system covers these essential elements in a manner that gives adequate confidence that the system can be assured to meet specified requirements.

3.4.3   The competencies required of the audit team shall be judged using the following as guidance:

    (a) identification of scope of certification using the Food Chain Categories,

    (b) the products produced by the client,

    (c) the processes used by the client,

    (d) the relevant regulatory requirements, and

    (e) the typical/specific hazards, critical control points and control measures associated with that combination of industry, product and process.

3.4.4   Where HACCP system or other related management system audits are conducted simultaneously or consecutively, there may be elements common to all systems. In determining auditor competence for common elements, the main principle is that the integrity of HACCP audit is maintained. This requires appropriate competence to be deployed for all audit activities. It remains a matter of judgement which aspects of a HACCP or other audit can be performed by an auditor whose training and background are from another discipline, and whether any supplementary knowledge and/or training are required.

3.5   Personnel Granting Certification

The certification body shall ensure that the personnel who take the decision on granting certification have the same education, food safety training, audit training and work experience as required for an auditor in one category (see Annex 1).

NOTE It is not mandatory for personnel granting certification to have or to maintain audit experience.

ANNEX 1 : SCOPE OF ACCREDITATION

Scope of accreditation to the certification bodies will be based on the Food Chain Category as in the following table:

Table 1- Scope of Accreditation

Category Codes	CATEGORIES	Sector (Examples)
C	processing 1 (perishable animal products) including all activities after farming eg. slaughtering, milking	Processing and preserving of meat and poultry and production of meat and poultry products, Processing and preserving fish, crustaceans and mollucs , Manufacture of meat, poultry, fish, crustaceans and mollucs based products eg bakery products, sandwiches Manufacture of dairy products Manufacture of eggs and egg product Wholesale and retail sale of food and traders of food including repacking of food
D	processing 2 (perishable vegetal products) including minimally processed products	Processing and preserving of fruit and vegetables, Manufacture of fruits and vegetables based products eg bakery products, sandwiches, salads, cut fruits and vegetables Wholesale and retail sale of food and traders of food including repacking of food
E	processing 3 (products with long shelf life at specified[1] temperatures)	Manufacture of vegetable and animal oils and fats, Manufacture of grain mill products, starches and starch products, Manufacture of farinaceous products , Manufacture of other food products eg sugar, cocoa, chocolate and sugar confectionery, salt, tea and coffee, condiments and seasonings, Manufacture of beverages including soft drinks, mineral waters and other bottled waters, Manufacture of edible birds nest and products Manufacture of homogenized food preparations and dietetic food, Manufacture of canned products, bottled products Wholesale and retail sale of food and traders of food including repacking of food
G	catering including mobile food service activities, hotel and related activities	Preparation and serving of meals and dishes including beverages, including all related activities eg event catering, holiday and short stay accommodation, camping grounds, recreational vehicle s parks and trailer parks, satellite or central kitchens, in flight kitchens restaurants, hostels, canteen

		repacking of food
L	food additives and supplements	Manufacture of food additives, vitamins, biocultures, Wholesale and retail sale of food and traders of food including repacking of food

NOTE : Specified[1] temperatures include ambient, chilled and frozen

ANNEX 2 : AUDITOR TIME

2.1 Minimum audit time

In determining the audit time needed for each site, as required in 9.1.4 of MS ISO/IEC 17021, the certification body should consider the minimum on-site duration for initial certification given in Table 2.

The minimum time includes stage 1 and stage 2 of the initial certification audit (see 9.2.3) but does not include the time for preparation of the audit nor for writing the audit report .

The minimum audit time is established for the audit of an HACCP system which includes only one HACCP plan. The minimum surveillance audit time should be one-third of the initial certification audit time, with a minimum of 0,5 audit days. The minimum renewal time should be two-thirds of the initial certification audit time, with a minimum of 1.5 audit days.

Where there is no relevant certified management system in place, additional time should be added for the audit. To be considered relevant, a management system certificate should cover the scope of food safety for the relevant product/ service. such as ISO 9001, ISO 22000, MS1514 and etc.

Other factors may necessitate increasing the minimum audit time (e.g. number of product types, number of product lines, product development, number of CCPs, building area, infrastructure, in-house laboratory testing, need for a translator).

2.2 Calculation of minimum initial certification audit time

2.2.1 Minimum audit time, Ts:

$Ts = (D + H + MS) * CC$

Where:

D is the basis on-site audit time;

H is the audit days for additional HACCP plan;

MS is the audit days for absence of relevant certified management system[2] ;

CC is the factor as multiplier for process or production complexity class.

Management system[2] : ISO 9001, ISO 22000, GMP or other systems related to food safety.

Table 2 — Minimum initial certification audit time

Category (See Annex 1)	D Basic on-site audit time (PRP + HACCP) (in audit days)	H For each additional HACCP Plan (in audit days)	CC (Complexity Class)	MS Absence of certified relevant management system (in audit days)
C	2.5	0.50	Low CC = 1	0.5
D	2.5	0.50		
E	3	0.50	Medium CC = 1.25	
G	4.0	0.50	High CC = 1.5	
L	3	0.5		

Table 2 is based on 3 primary complexity classess of the nature of the processes or production of an organisation that fundamentally affect the HACCP Auditor time. They are:

High CC− Overall large establishments with multiple operations involved in the production of food. Examples of the food product in this category are refined sugar, refined oil, product in hermatically sealed containers, pasteurized, sterilized, UHT products, food court.

Medium CC − Overall medium establishments with multiple operations involved in the production of food. Examples of the food products in this category are flour, rice including milled rice, pasta, bread, smoked meat, cured fish, smoked fish, fish balls and fish cakes, dried vegetables, kitchens (hotels, restaurants, catering)

Low CC − Micro/small establishments with simple operations involved in the production. Examples of the food products in this category are ground spices, salt, cordials, salted or pickled products, ready cut prepackaged foods, raw salads, frozen or chilled raw meat, poultry or fish (only cleaned and cutting before packaging)

2.2.2   The examples of the food products in each complexity class are as guidances. However, the certification body shall provide justification if deviation is made in the complexity class.