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

ACB-GOOD MANUFACTURING PRACTICE FOR FOOD (GMP)

Issue 1, 18 June 2013

STANDARDS MALAYSIA REQUIREMENTS FOR THE ACCREDITATION OF BODIES OPERATING CERTIFICATION OF GOOD MANUFACTURING PRACTICE FOR FOOD TO MS 1514

Authority To Issue

Director General
Department of Standards Malaysia

STANDARDS MALAYSIA REQUIREMENTS FOR THE ACCREDITATION OF BODIES OPERATING CERTIFICATION OF GOOD MANUFACTURING PRACTICE FOR FOOD TO MS 1514

CONTENTS **PAGE**

STANDARDS MALAYSIA REQUIREMENTS FOR THE ACCREDITATION OF BODIES OPERATING CERTIFICATION OF GOOD MANUFACTURING PRACTICE FOR FOOD TO MS 1514

SECTION 0: INTRODUCTION

0.1 Background

Effective hygiene control is vital to avoid foodborne illnesses, food spoilages, food contaminations and foodborne injuries. Poor hygiene may spread illnesses and impose life-threatening risks to the public. Globally, foodborne incidents can damage frequency of foreign visits and travels leading to collapse of trade and tourism. This may lead to loss of earnings, unemployment and litigation.

Good Manufacturing Practice (GMP) sets regulations, codes and guidelines that control the operational conditions within a food establishment allowing for the production of safe food. This practice can assists manufacturers of food products and food related products to provide assurance that their products are manufactured in a hygienic manner as well as complying to the best manufacturing practices.

GMP is also one of the pre-requisite programmes (PRP) for the establishment of the Hazard Analysis Critical Control Points (HACCP) System. A HACCP System, on the other hand is a system, which identifies, evaluates and controls hazards which are significant for food safety.

MS 1514: Good Manufacturing Practice (GMP) for Food lays a firm foundation on good manufacturing practice (GMP) to ensure food hygiene and safety. The standard follows the food chain from incoming materials through to the customers, highlighting the key hygiene controls at each stage.

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-GMP which was developed by the technical working group (TWG) on GMP for Food, provides interpretations to the applications of MS ISO/IEC 17021 for the accreditation of the GMP 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 organisations for their Good Manufacturing Practices (GMP) for the food sector only.

It is important to understand that these are the requirements that have to be met by certification bodies. These are not requirements that have to be met by the organisations that are audited by the certification bodies. The requirements that must be met by the organisations can be found in the appropriate certification standard.

Accreditation in compliance with these requirements acknowledges that the certification bodies possess the necessary competence and reliability to operate a GMP 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 procedure.

SECTION 1: GENERAL

1.1. Scope

Where MS ISO/IEC 17021 refers to management systems it shall be read as a reference to GMP. The certification standard to be used shall be MS 1514. The scope of certification shall be applicable to any organization in demonstrating conformity to the requirements for food hygiene according to GMP to ensure the safety of foodstuffs 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:

Normative :

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

MS ISO/IEC 17021 - Conformity assessment – Requirements for bodies providing audit and 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

Food Act 1983 & Food Regulations 1985

Food Hygiene Regulation 2009

Informative :

ISO 9000 – Quality Management Systems – Fundamental and Vocabulary

ISO 9001 – Quality Management Systems – Requirements

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

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

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

ISO/TS 22002 – 1: Prerequisite programmes on food safety for food manufacturing
NOTE: For undated references, the latest edition of the referenced document (including any amendments) applies.

1.3. Definitions

The following definitions apply :

Effective Number of personnel	:	The effective number of personnel consist of a full time personnel involved within the scope of certification including those working on each shift. Non-permanent (seasonal, temporary and contracted personnel) and part time personnel who will be present at the time of the audit shall be included in this number.
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 Hygiene	:	All measures and conditions necessary to control hazards and to ensure safety and suitability of food for human consumption taking into account its intended use.
Food safety	:	Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
Good Manufacturing Practice (GMP)	:	A set of regulations, codes, and guidelines that controls the operational conditions within a food establishment allowing for the production of safe food.

High risk area	**:**	A physically segregated area, designed to a high standard of hygiene, where practices relating To personnel, ingredients, equipment, packaging & environment aim to prevent Product contamination by pathogenic micro-organisms.
Nonconformity	**:**	The absence of, or the failure to implement and maintain, one or more required GMP elements, or situation which would, on the basis of available objective evidence or evaluation, raise doubt as to the safety of the food.
Validation	**:**	Obtaining evidence that the elements of the GMP are effective.
Verification	**:**	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with GMP.

1.4 Accredited Scope

The accredited scope of a certification body is expressed in terms of the food premises for the manufacture / production , including food services in which the requirements for a GMP are expressed.

1.5 Consultancy

The term “management system consultancy” (as in MS ISO/IEC 17021) in this GMP programme can be refered to all elements of GMP, hazard analysis, consultancy, food safety system related consultancy or any management system consultancy related to food safety.

SECTION 2: REQUIREMENTS FOR CERTIFICATION BODIES

2.1 Application Stage

The certification body shall require the applicant organisation to provide detailed information concerning GMP elements, description of products, process flow, plant layout, number of 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 GMP in the context of the organization’s infrastructure, layout, food safety hazard identification, 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 and complied with the requirements that are appropriate to the business (e.g. regulatory and statutory requirements),

b) the GMP includes adequate processes that control the operational condition for the production of safe food including control measures.

c) the GMP is designed to achieve the organization's scope for the production of safe food,

d) food safety legislation is in place for the relevant sector(s) of the organization,

e) the GMP implementation justifies proceeding to the audit (stage 2),

f) the control measure have been validated ,

g) the GMP system has been verified,

h) the GMP documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties and

i) additional documentation needs to be reviewed and/or other knowledge needs to be obtained in advance before stage 2.

2.3 Stage 2 Audit

The stage 2 audit shall take place at the site(s) of the client. It shall include at least the following:

a) review and verify implementation to meet the requirement of each of the GMP elements as defined in the MS 1514 standard,
b) verify the organisations GMP and performance with regards to compliance with legal requirements,

c) verify operational control of the organisations processes,

d) verify the effectiveness of the control measures,

e) review self inspection and internal auditing,

f) review management responsibility to determine the suitability and effectiveness of the GMP

Note: Any part of the GMP 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 GMP 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.

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

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 high risk area(s).

Surveillance audit shall also include a review of:

a) nonconformities resulting from previous audit,

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

c) changes in production systems and/or equipment,

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

e) training,

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

g) changes in customer and regulatory requirements,

h) new knowledge on hazards,

i) verification activities, and

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

2.4.1 The conditions for granting, maintaining, extending, reducing, withdrawing or suspending of certification shall incorporate or otherwise address any relevant regulatory requirements, and withdrawal of certification relating to GMP shall be communicated to relevant regulators.

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

2.4.3 The report by the audit team shall include comments on the effectiveness of the GMP implementation, and other issues relevant to food hygiene and safety.

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 GMP 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 GMP in order to enhance overall performance;

c) whether the operation of the certified GMP contributes to the achievement of the food safety policy and objectives.

d) the effectiveness of operational control(s) 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 responsed to an application for extension to the scope of a certification already granted.

2.6.1.2 The certification body shall, in response to an application for extension to the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. The granting of extension of scope may need on site visit to verify changes for example in infrastructure, processing machine equipment, production capacity and warehousing facilities. This may 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 and hygiene training

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

a) good hygiene practice and good manufacturing practice, MS 1514 or equivalent and,

b) food safety management

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 (see Annex 1),

b) assessment of applicant products, processes and practices,

c) deployment of GMP 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 auditors' competence.

3.2.2 Education

The certification body shall ensure that auditors have the knowledge corresponding to a post-secondary education for examples related relevant science based disciplines. 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 GMP 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 and hygiene training

The certification body shall ensure that auditors have successfully completed training in good hygiene practice, good manufacturing practice and food hygiene requirements. The training course shall be conducted by trainer certified by Ministry of Health (MOH).

3.2.3.2 The CB shall also ensured 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) relevant GMP standards (MS 1514 or equivalent),

c) technical operation for specific sector where required

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 four years of full-time work experience in the food-chain-related industry, including at least two 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 to be a GMP auditor, the certification body shall ensure that within the last three years the auditor has performed at least twelve GMP and/or GMP elements of HACCP/FSMS audit days in at least four organizations under the leadership of a qualified auditor.
Note: A qualified HACCP/FSMS auditor is exempted from this requirement.

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 months of work experience in the new category, or
- four GMP audits under the supervision of a qualified auditor in the new category.

For maintaining the qualification of the auditor, the certification body shall ensure that auditors have performed a minimum of five external GMP and/or GMP elements of HACCP/FSMS audits per year consisting of at least ten audit days

3.2.7 Knowledge on Regulatory Requirement

The competent personnel shall be aware of current regulatory requirements, GMP 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 hygiene and sanitation applicable to the sector. The certification body shall ensure that technical experts have work experience in the sector. The certification body shall ensure that technical experts demonstrate the ability to provide expertise in the sector.

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 GMP in specific sector they are auditing. It shall be able to determine whether or not a particular GMP adequately complies with the requirements of the GMP standard.

3.4.2 The above requires that the audit team, deployed in each case by a certification body to conduct an audit of a organisation's GMP, needs to know the requirements stipulated in the GMP standard. A requirement is essential where failure of any GMP element results in an unacceptable practice. The audit team shall have the necessary competence, including sector or regulatory knowledge, to determine whether the practice covers these essential elements in a manner that gives adequate confidence that GMP 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,

(b) products produced by the organisation,

(c) the processes and control measures used by the organisation, and

(d) the relevant regulatory requirements

3.4.4 Where GMP 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 each audit is maintained. This requires appropriate competence to be deployed for all audit activities. It remains a matter of judgement which aspects of a GMP 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 knowledge and training in MS 1514.

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 Category Codes 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 vehicles 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, MS ISO/IEC 17021) but does not include the time for preparation of the audit nor for writing the audit report .

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 1.0 audit day.

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 GMP elements for the relevant product / service.

Other factors may necessitate increasing the minimum audit time (e.g. building area, infrastructure, number of food handlers, complexity of operation, 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 + MS + FTE) * CC
Where:

D is the basis on-site audit time;

FTE is the audit days for category of establishments based on full time employees

MS is the audit days for absence of relevant management system;

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

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.

Table 2 — Minimum initial certification audit time

Category (See Annex 1)	**D Basic on-site audit time (PRP)** (in audit days)	**FTE For each category of establishment based on effective number of employees** (in audit days)	**CC (Complexity Class)**	**MS Absence of certified relevant management system** (in audit days)
C	1	Micro = < 50 (0.5) Small = 51 – 150 (0.75) Medium = 151 – 250 (1.0) Large = >250 (1.25)	Low CC = 1 Medium CC = 1.25 High CC = 1.5	0.5
D	1			
E	1			
G	1.5			
L	1			

Table 2 is based on 3 primary complexity classes of the nature of the processes or production of an organisation that fundamentally affect the GMP audit 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)