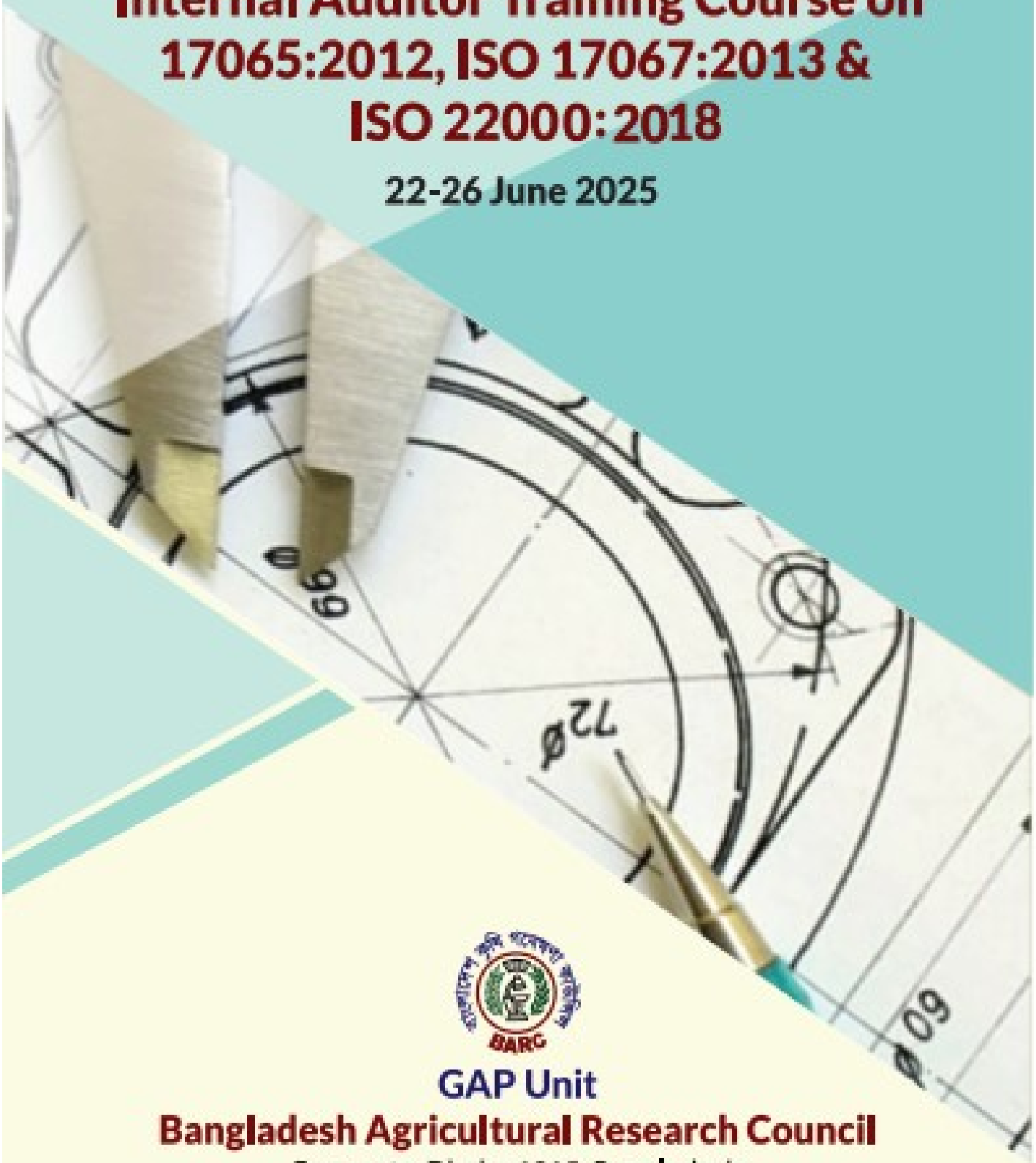
ToT Manual

Internal Auditor Training Course on 17065:2012, ISO 17067:2013 & ISO 22000:2018

22-26 June 2025



GAP Unit

Bangladesh Agricultural Research Council

Farmgate, Dhaka-1215, Bangladesh

প্রশিক্ষণ ম্যানুয়েল

Internal Auditor Training Course
on
ISO 17065:2012, 17067:2013 & 22000:2018

সংকলন ও সম্পাদনা

ড. মোঃ আবদুছ ছালাম

ড. যাকীয়াহ্ রহমান মনি

ড. মিয়া সাঈদ হাসান

GAP ইউনিট

বাংলাদেশ কৃষি গবেষণা কাউন্সিল

ফার্মগেট, ঢাকা-১২১৫।

জুন ২০২৫

প্রকাশকাল
জুন ২০২৫ খ্রি.

মুদ্রণ
৬০ কপি

প্রকাশনায়
GAP ইউনিট
বাংলাদেশ কৃষি গবেষণা কাউন্সিল
ফার্মগেট, ঢাকা-১২১৫।

কভার ডিজাইন
মোহাম্মদ নাজমুল ইসলাম
গ্রাফিক্স ডিজাইনার, বিএআরসি

অর্থায়নে
"Program on Agricultural and Rural Transformation for Nutrition, Entrepreneurship, and. Resilience in Bangladesh (PARTNER)", APCU-BARC.

সূচিপত্র

INTERNATIONAL STANDARD

ISO/IEC 17065

First edition
2012-09-15

Conformity assessment — Requirements for bodies certifying products, processes and services

Évaluation de la conformité — Exigences pour les organismes certifiant les produits, les procédés et les services

Reference number
ISO/IEC 17065:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards are circulated to the national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 17065 was prepared by the ISO Committee on conformity assessment (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17065 cancels and replaces ISO/IEC Guide 65:1996, which has been technically revised.

The following major changes have been made compared with ISO/IEC Guide 65:1996:

— restructuring of this International Standard based on the common structure adopted by ISO/CASCO;

— modifications based on ISO/PAS 17001, ISO/PAS 17002, ISO/PAS 17003, ISO/PAS 17004 and ISO/PAS 17005;

— introduction of the ISO/IEC 17000 functional approach in the process requirements of Clause 7;

— information on the application of this International Standard for processes and services in Annex B;

— revision of the terms and definitions in Clause 3;

— improvement of the impartiality requirements (mechanism);

— consolidation of the management system requirements in Clause 8;

— inclusion of principles for product certification bodies and their activities in Annex A;

— improvement by taking into account IAF GD 5;

— inclusion of a reference to certification schemes, for which further information is provided in ISO/IEC 17067.

Introduction

The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to:

a) the clients of the certification bodies;

b) the customers of the organizations whose products, processes or services are certified;

c) governmental authorities;

d) non-governmental organizations; and

e) consumers and other members of the public.

Interested parties can expect or require the certification body to meet all the requirements of this International Standard as well as when relevant, those of the certification scheme.

Certification of products, processes or services is a means of providing assurance that they comply with specified requirements in standards and other normative documents. Some product, process or service certification schemes may include initial testing or inspection and assessment of its suppliers' quality management systems, followed by surveillance that takes into account the quality management system and the testing or inspection of samples from the production and the open market. Other schemes rely on initial testing and surveillance testing, while still others comprise type testing only.

This International Standard specifies requirements, the observance of which is intended to ensure that certification bodies operate certification schemes in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of certified products, processes and services on a national and international basis and so furthering international trade. This International Standard can be used as a criteria document for accreditation or peer assessment or designation by governmental authorities, scheme owners and others.

The requirements contained in this International Standard are written, above all, to be considered as general criteria for certification bodies operating product, process or service certification schemes; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account. Annex A contains principles relating to certification bodies and certification activities that they provide.

This International Standard does not set requirements for schemes and how they are developed and is not intended to restrict the role or choice of scheme owners, however scheme requirements should not contradict or exclude any of the requirements of this International Standard.

Statements of conformity to the applicable standards or other normative documents can be in the form of certificates and/or marks of conformity. Schemes for certifying particular products or product groups, processes and services to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

While this International Standard is concerned with third parties providing product, process or service certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

Conformity assessment — Requirements for bodies certifying products, processes and services

1 Scope

This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies. Certification bodies operating to this International Standard need not offer all types of products, processes and services certification. Certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000:2004, definition 5.5).

In this International Standard, the term “product” can be read as “process” or “service”, except in those instances where separate provisions are stated for “processes” or “services” (see Annex B).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

3.1
client
organization or person responsible to a certification body for ensuring that **certification requirements** (3.7), including **product requirements** (3.8), are fulfilled

NOTE Whenever the term “client” is used in this International Standard, it applies to both the “applicant” and the “client”, unless otherwise specified.

3.2
consultancy
participation in

a) the designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or

b) the designing, implementing, operating or maintaining of a certified process or a process to be certified, or

c) the designing, implementing, providing or maintaining of a certified service or a service to be certified

NOTE In this International Standard, the term "consultancy" is used in relation to activities of certification bodies, personnel of certification bodies and organizations related or linked to certification bodies.

3.3
evaluation
combination of the selection and determination functions of conformity assessment activities

NOTE The selection and determination functions are specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

3.4
product
result of a process

NOTE 1 Four generic product categories are noted in ISO 9000:2005:

— services (e.g. transport) (see definition in 3.6);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine, mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

NOTE 2 Products include results of natural processes, such as growth of plants and formation of other natural resources.

NOTE 3 Adapted from ISO/IEC 17000:2004, definition 3.3.

3.5
process
set of interrelated or interacting activities which transforms inputs into outputs

EXAMPLES Welding engineering processes; heat treatment processes; manufacturing processes requiring confirmation of process capability (e.g. operating or producing product within specified tolerances); food production processes; plant growth processes.

NOTE Adapted from ISO 9000:2005, definition 3.4.1.

3.6
service
result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

NOTE 1 Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.2.

3.7
certification requirement
specified requirement, including **product requirements** (3.8), that is fulfilled by the **client** (3.1) as a condition of establishing or maintaining certification

NOTE Certification requirements include requirements imposed on the client by the certification body [usually via the certification agreement (see 4.1.2)] to meet this International Standard, and can also include requirements imposed on the client by the certification scheme. "Certification requirements", as used in this International Standard, do not include requirements imposed on the certification body by the certification scheme.

EXAMPLE The following are certification requirements that are not product requirements:

— completing the certification agreement;

— paying fees;

— providing information about changes to the certified product;

— providing access to certified products for surveillance activities.

3.8
product requirement
requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme

NOTE Product requirements can be specified in normative documents such as regulations, standards and technical specifications.

3.9
certification scheme
certification system related to specified products, to which the same specified requirements, specific rules and procedures apply

NOTE 1 Adapted from ISO/IEC 17000:2004, definition 2.8.

NOTE 2 A "certification system" is a "conformity assessment system", which is defined in ISO/IEC 17000:2004, definition 2.7.

NOTE 3 The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

NOTE 4 General guidance for the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

3.10
scope of certification
identification of

— the product(s), process(es) or service(s) for which the certification is granted,

— the applicable certification scheme, and

— the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply

3.11
scheme owner
person or organization responsible for developing and maintaining a specific **certification scheme** (3.9)

NOTE The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

3.12
certification body
third-party conformity assessment body operating certification schemes

NOTE A certification body can be non-governmental or governmental (with or without regulatory authority).

3.13
impartiality
presence of objectivity

NOTE 1 Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the body.

NOTE 2 Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

4 General requirements

4.1 Legal and contractual matters

4.1.1 Legal responsibility

The certification body shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities.

NOTE A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

4.1.2 Certification agreement

4.1.2.1 The certification body shall have a legally enforceable agreement for the provision of certification activities to its clients. Certification agreements shall take into account the responsibilities of the certification body and its clients.

4.1.2.2 The certification body shall ensure its certification agreement requires that the client comply at least, with the following:

a) the client always fulfils the certification requirements (see 3.7), including implementing appropriate changes when they are communicated by the certification body (see 7.10);

b) if the certification applies to ongoing production, the certified product continues to fulfil the product requirements (see 3.8);

c) the client makes all necessary arrangements for

   1) the conduct of the evaluation (see 3.3) and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors;

   2) investigation of complaints;

   3) the participation of observers, if applicable;

d) the client makes claims regarding certification consistent with the scope of certification (see 3.10);

e) the client does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification that the certification body may consider misleading or unauthorized;

f) upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure;

g) if the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;

h) in making reference to its product certification in communication media such as documents, brochures or advertising, the client complies with the requirements of the certification body or as specified by the certification scheme;

i) the client complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product;

NOTE See also ISO/IEC 17030, ISO/IEC Guide 23 and ISO Guide 27.

j) the client keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the certification body when requested, and

1) takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;

2) documents the actions taken;

NOTE Verification of item j) by the certification body can be specified in the certification scheme.

k) the client informs the certification body, without delay, of changes that may affect its ability to conform with the certification requirements.

NOTE Examples of changes can include the following:

— the legal, commercial, organizational status or ownership,

— organization and management (e.g. key managerial, decision-making or technical staff),

— modifications to the product or the production method,

— contact address and production sites,

— major changes to the quality management system.

4.1.3 Use of license, certificates and marks of conformity

4.1.3.1 The certification body shall exercise the control as specified by the certification scheme over ownership, use and display of licenses, certificates, marks of conformity, and any other mechanisms for indicating a product is certified.

NOTE 1 Guidance on the use of certificates and marks permitted by the certification body can be obtained from ISO/IEC Guide 23.

NOTE 2 ISO/IEC 17030 provides requirements for the use of third-party marks.

4.1.3.2 Incorrect references to the certification scheme, or misleading use of licenses, certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.

NOTE Such actions are addressed in ISO Guide 27 and can include corrective actions, withdrawal of certificate, publication of the transgression and, if necessary, legal action.

4.2 Management of impartiality

4.2.1 Certification activities shall be undertaken impartially.

4.2.2 The certification body shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.2.3 The certification body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, from its relationships, or from the relationships of its personnel (see 4.2.12). However, such relationships may not necessarily present a certification body with a risk to impartiality.

NOTE 1 A relationship presenting a risk to impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.

NOTE 2 Identifying risks does not imply risk assessments as stated in ISO 31000.

4.2.4 If a risk to impartiality is identified, the certification body shall be able to demonstrate how it eliminates or minimizes such risk. This information shall be made available to the mechanism specified in 5.2.

4.2.5 The certification body shall have top management commitment to impartiality.

4.2.6 The certification body and any part of the same legal entity and entities under its organizational control (see 7.6.4) shall not:

a) be the designer, manufacturer, installer, distributer or maintainer of the certified product;

b) be the designer, implementer, operator or maintainer of the certified process;

c) be the designer, implementer, provider or maintainer of the certified service;

d) offer or provide consultancy (see 3.2) to its clients;

e) offer or provide management system consultancy or internal auditing to its clients where the certification scheme requires the evaluation of the client's management system.

NOTE 1 This does not preclude the following:

— the possibility of exchange of information (e.g. explanations of findings or clarifying requirements) between the certification body and its clients;

— the use, installing and maintaining of certified products which are necessary for the operations of the certification body.

NOTE 2 "Management system consultancy" is defined in ISO/IEC 17021:2011, definition 3.3.

4.2.7 The certification body shall ensure that activities of separate legal entities, with which the certification body or the legal entity of which it forms a part has relationships, do not compromise the impartiality of its certification activities.

NOTE See 4.2.3, Note 1.

4.2.8 When the separate legal entity in 4.2.7 offers or produces the certified product (including products to be certified) or offers or provides consultancy (see 3.2), the certification body's management personnel and personnel in the review and certification decision-making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the certification body, the review, or the certification decision.

NOTE For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.

4.2.9 The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides consultancy (see 3.2). A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

4.2.10 Within a period specified by the certification body, personnel shall not be used to review or make a certification decision for a product for which they have provided consultancy (see 3.2).

NOTE 1 The period can be specified in the certification scheme or, if specified by the certification body, it reflects a period that is long enough to ensure that the review or decision does not compromise impartiality. A specified period of two years is often used.

NOTE 2 For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.

4.2.11 The certification body shall take action to respond to any risks to its impartiality, arising from the actions of other persons, bodies or organizations, of which it becomes aware.

4.2.12 All certification body personnel (either internal or external) or committees who could influence the certification activities shall act impartially.

4.3 Liability and financing

4.3.1 The certification body shall have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations.

4.3.2 The certification body shall have the financial stability and resources required for its operations.

4.4 Non-discriminatory conditions

4.4.1 The policies and procedures under which the certification body operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this International Standard.

4.4.2 The certification body shall make its services accessible to all applicants whose activities fall within the scope of its operations.

4.4.3 Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions.

NOTE A certification body can decline to accept an application or maintain a contract for certification from a client when fundamental or demonstrated reasons exist, such as the client participating in illegal activities, having a history of repeated non-compliances with certification/product requirements, or similar client-related issues.

4.4.4 The certification body shall confine its requirements, evaluation, review, decision and surveillance (if any) to those matters specifically related to the scope of certification.

4.5 Confidentiality

4.5.1 The certification body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of certification activities. Except for information that the client makes publicly available, or when agreed between the certification body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. The certification body shall inform the client, in advance, of the information it intends to place in the public domain.

4.5.2 When the certification body is required by law or authorized by contractual arrangements to release confidential information, the client or person concerned shall, unless prohibited by law, be notified of the information provided.

4.5.3 Information about the client obtained from sources other than the client (e.g. from the complainant or from regulators) shall be treated as confidential.

4.6 Publicly available information

The certification body shall maintain (through publications, electronic media or other means), and make available upon request, the following:

a) information about (or reference to) the certification scheme(s), including evaluation procedures, rules and procedures for granting, for maintaining, for extending or reducing the scope of, for suspending, for withdrawing or for refusing certification;

b) a description of the means by which the certification body obtains financial support and general information on the fees charged to applicants and to clients;

c) a description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted;

d) information about procedures for handling complaints and appeals.

5 Structural requirements

5.1 Organizational structure and top management

5.1.1 Certification activities shall be structured and managed so as to safeguard impartiality.

5.1.2 The certification body shall document its organizational structure, showing duties, responsibilities and authorities of management and other certification personnel and any committees. When the certification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

5.1.3 The management of the certification body shall identify the board, group of persons, or person having overall authority and responsibility for each of the following:

a) development of policies relating to the operation of the certification body;

b) supervision of the implementation of the policies and procedures;

c) supervision of the finances of the certification body;

d) development of certification activities;

e) development of certification requirements;

f) evaluation (see 7.4);

g) review (see 7.5);

h) decisions on certification (see 7.6);

i) delegation of authority to committees or personnel, as required, to undertake defined activities on its behalf;

j) contractual arrangements;

k) provision of adequate resources for certification activities;

l) responsiveness to complaints and appeals;

m) personnel competence requirements;

n) management system of the certification body (see Clause 8).

5.1.4 The certification body shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification process (see Clause 7). Such committees shall be free from any commercial, financial and other pressures that might influence decisions. The certification body shall retain authority to appoint and withdraw members of such committees.

5.2 Mechanism for safeguarding impartiality

5.2.1 The certification body shall have a mechanism for safeguarding its impartiality. The mechanism shall provide input on the following:

a) the policies and principles relating to the impartiality of its certification activities;

b) any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent impartial provision of certification activities;

c) matters affecting impartiality and confidence in certification, including openness.

NOTE 1 Other tasks or duties (e.g. taking part in the decision-making process) can be assigned to the mechanism, provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

NOTE 2 A possible mechanism can be a committee established by one or more certification bodies, a committee implemented by a scheme owner, a governmental authority or an equivalent party.

NOTE 3 A single mechanism for several certification schemes can satisfy this requirement.

NOTE 4 If the certification body also provides management systems certification, a committee that fulfils ISO/IEC 17021:2011, 6.2, can also fulfil this subclause (5.2) providing that all the requirements of 5.2 have been met.

5.2.2 The mechanism shall be formally documented to ensure the following:

a) a balanced representation of significantly interested parties, such that no single interest predominates (internal or external personnel of the certification body are considered to be a single interest, and shall not predominate);

b) access to all the information necessary to enable it to fulfil all its functions.

5.2.3 If the top management of the certification body does not follow the input of this mechanism, the mechanism shall have the right to take independent action (e.g. informing authorities, accreditation bodies, stakeholders). In taking appropriate action, the confidentiality requirements of 4.5 relating to the client and certification body shall be respected.

Input that is in conflict with the operating procedures of the certification body or other mandatory requirements should not be followed. Management should document the reasoning behind the decision to not follow the input and maintain the document for review by appropriate personnel.

5.2.4 Although every interest cannot be represented in the mechanism, a certification body shall identify and invite significantly interested parties.

NOTE 1 Such interested parties can include clients of the certification body, customers of clients, manufacturers, suppliers, users, conformity assessment experts, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, and representatives of non-governmental organizations, including consumer organizations. It can be sufficient to have one representative of each interested party in the mechanism.

NOTE 2 These interests can be limited, depending on the nature of the certification scheme.

6 Resource requirements

6.1 Certification body personnel

6.1.1 General

6.1.1.1 The certification body shall employ, or have access to, a sufficient number of personnel to cover its operations related to the certification schemes and to the applicable standards and other normative documents.

NOTE The personnel include those normally working for the certification body, as well as persons working under an individual contract or a formal agreement that places them within the management control and systems/procedures of the certification body (see 6.1.3).

6.1.1.2 The personnel shall be competent for the functions they perform, including making required technical judgments, defining policies and implementing them.

6.1.1.3 Personnel, including any committee members, personnel of external bodies, or personnel acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification activities, except as required by law or by the certification scheme.

6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1 The certification body shall establish, implement and maintain a procedure for management of competencies of personnel involved in the certification process (see Clause 7). The procedure shall require the certification body to:

a) determine the criteria for the competence of personnel for each function in the certification process, taking into account the requirements of the schemes;

b) identify training needs and provide, as necessary, training programmes on certification processes, requirements, methodologies, activities and other relevant certification scheme requirements;

c) demonstrate that the personnel have the required competencies for the duties and responsibilities they undertake;

d) formally authorize personnel for functions in the certification process;

e) monitor the performance of the personnel.

6.1.2.2 The certification body shall maintain the following records on the personnel involved in the certification process (see Clause 7):

a) name and address;

b) employer(s) and position held;

c) educational qualification and professional status;

d) experience and training;

e) the assessment of competence;

f) performance monitoring;

g) authorizations held within the certification body;

h) date of most recent updating of each record.

6.1.3 Contract with the personnel

The certification body shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to the following:

a) to comply with the rules defined by the certification body, including those relating to confidentiality (see 4.5) and independence from commercial and other interests;

b) to declare any prior and/or present association on their own part, or on the part of their employer, with:

   1) a supplier or designer of products, or

   2) a provider or developer of services, or

   3) an operator or developer of processes

   to the evaluation or certification of which they are to be assigned;

c) to reveal any situation known to them that may present them or the certification body with a conflict of interest (see 4.2).

Certification bodies shall use this information as input into identifying risks to impartiality raised by the activities of such personnel, or by the organizations that employ them (see 4.2.3).

6.2 Resources for evaluation

6.2.1 Internal resources

When a certification body performs evaluation activities, either with its internal resources or with other resources under its direct control, it shall meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.

NOTE Examples of reasons as to why some requirements are not applicable include the following:

— expertise is available within the certification body when using the results of the evaluation activity;

— the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);

— a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision.

6.2.2 External resources (outsourcing)

6.2.2.1 The certification body shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.

NOTE 1 Examples of reasons as to why some requirements are not applicable include the following:

— expertise is available within the certification body when using the results of the evaluation activity;

— the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);

— a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision.

NOTE 2 This can include outsourcing to other certification bodies. Use of external personnel under contract is not outsourcing.

NOTE 3 For the purposes of this International Standard, the terms “outsourcing” and “subcontracting” are considered to be synonyms.

6.2.2.2 Where evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), the certification body shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence.

6.2.2.3 The certification body shall have a legally binding contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest as specified in 6.1.3, item c).

6.2.2.4 The certification body shall:

a) take responsibility for all activities outsourced to another body;

b) ensure that the body that provides outsourced services, and the personnel that it uses, are not involved, either directly or through any other employer, in such a way that the credibility of the results could be compromised;

c) have documented policies, procedures and records for the qualification, assessing and monitoring of all bodies that provide outsourced services used for certification activities;

d) maintain a list of approved providers of outsourced services;

e) implement corrective actions for any breaches of the contract in 6.2.2.3 or other requirements in 6.2.2 of which it becomes aware;

f) inform the client in advance of outsourcing activities, in order to provide the client with an opportunity to object.

NOTE If the qualification, assessing and monitoring of the bodies that provide outsourced services are performed by other organizations (e.g. by accreditation bodies, peer assessment bodies or governmental authorities), the certification body can take this qualification and monitoring into account provided that:

— it is provided for within the scheme requirements;

— the scope is applicable to the work being undertaken;

— the validity of the qualification, assessing and monitoring arrangements is verified at a periodicity determined by the certification body.

7 Process requirements

7.1 General

7.1.1 The certification body shall operate one or more certification scheme(s) covering its certification activities.

NOTE 1 The elements of such schemes can be coupled with surveillance of production, or with the assessment and surveillance of the client's management system, or both.

NOTE 2 General guidance on the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

7.1.2 The requirements against which the products of a client are evaluated shall be those contained in specified standards and other normative documents.

NOTE Guidance for developing normative documents suitable for this purpose is contained in ISO/IEC 17007.

7.1.3 If explanations are required as to the application of these documents (see 7.1.2) for a specific certification scheme, they shall be formulated by relevant and impartial persons or committees, possessing the necessary technical competence, and shall be made available by the certification body upon request.

7.2 Application

For application, the certification body shall obtain all the necessary information to complete the certification process in accordance with the relevant certification scheme.

NOTE 1 The following are examples of necessary information:

— the product(s) to be certified;

— the standards and/or other normative documents for which the client is seeking certification (see 7.1.2);

— the general features of the client, including its name and the address(es) of its physical location(s), significant aspects of its process and operations (if required by the relevant certification scheme), and any relevant legal obligations;

— general information concerning the client, relevant to the field of certification for which the application is made, such as the client's activities, its human and technical resources, including laboratories and/or inspection facilities, and its functions and relationship in a larger corporation, if any;

— information concerning all outsourced processes used by the client that will affect conformity to requirements; if the client has identified a legal entity/entities for producing the certified product(s) that is different from the client, then the certification body can establish appropriate contractual controls over the legal entity/entities concerned, if necessary for effective surveillance; if such contractual controls are needed, they can be established prior to providing formal certification documentation (see 7.7);

— all other information needed in accordance with the relevant certification requirements, such as information for initial evaluation and surveillance activities, e.g. the locations where the certified product(s) are produced and contact personnel at these locations.

NOTE 2 A variety of media and mechanisms can be used to collect this information at various times, including an application form. Such information gathering can be in conjunction with, or separate from, the completion of the legally binding agreement (the certification agreement) specified in 4.1.2.

NOTE 3 Application for an extension of the certification scope could involve similar products, different locations, etc.

7.3 Application review

7.3.1 The certification body shall conduct a review of the information obtained (see 7.2) to ensure that:

a) the information about the client and the product is sufficient for the conduct of the certification process;

b) any known difference in understanding between the certification body and the client is resolved, including agreement regarding standards or other normative documents;

c) the scope of certification (see 3.10) sought is defined;

d) the means are available to perform all evaluation activities;

e) the certification body has the competence and capability to perform the certification activity.

7.3.2 The certification body shall have a process to identify when the client's request for certification includes

— a type of product, or

— a normative document, or

— a certification scheme

with which the certification body has no prior experience,

NOTE Products can be considered to be of the same type when the knowledge of the requirements, characteristics and technology related to one product is sufficient to understand the requirements, characteristics and technology of another product.

7.3.3 In these cases (see 7.3.2), the certification body shall ensure it has the competence and capability for all the certification activities it is required to undertake, and it shall maintain a record of the justification for the decision to undertake certification.

7.3.4 The certification body shall decline to undertake a specific certification if it lacks any competence or capability for the certification activities it is required to undertake.

7.3.5 If the certification body relies on certifications it has already granted to the client, or has already granted to other clients, to omit any activities, then the certification body shall reference the existing certification(s) in its records. If requested by the client, the certification body shall provide justification for omission of activities.

7.4 Evaluation

7.4.1 The certification body shall have a plan for the evaluation activities to allow for the necessary arrangements to be managed.

NOTE Depending on the characteristics of the certification scheme and the product requirements, the plan can be either a generic plan applicable to all activities, including evaluation of the quality management system, when applicable, or a specific one for a particular activity, or a combination of both.

7.4.2 The certification body shall assign personnel to perform each evaluation task that it undertakes with its internal resources (see 6.2.1).

NOTE Outsourced tasks are completed by personnel usually assigned by the organization to which the task is outsourced. Such personnel are not normally assigned by the certification body.

7.4.3 The certification body shall ensure all necessary information and/or documentation is made available for performing the evaluation tasks.

NOTE The evaluation tasks can include activities such as design and documentation review, sampling, testing, inspection and audit.

7.4.4 The certification body shall carry out the evaluation activities that it undertakes with its internal resources (see 6.2.1) and shall manage outsourced resources (see 6.2.2) in accordance with the evaluation plan (see 7.4.1). The products shall be evaluated against the requirements covered by the scope of certification and other requirements specified in the certification scheme.

7.4.5 The certification body shall only rely on evaluation results related to certification completed prior to the application for certification, where it takes responsibility for the results and satisfies itself that the body that performed the evaluation fulfils the requirements contained in 6.2.2 and those specified by the certification scheme.

NOTE This can include work carried out under recognition agreements between certification bodies.

7.4.6 The certification body shall inform the client of all nonconformities.

7.4.7 If one or more nonconformities have arisen, and if the client expresses interest in continuing the certification process, the certification body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

7.4.8 If the client agrees to completion of the additional evaluation tasks, the process specified in 7.4 shall be repeated to complete the additional evaluation tasks.

7.4.9 The results of all evaluation activities shall be documented prior to review (see 7.5).

NOTE 1 This documentation can provide an opinion as to whether product requirements (including requirements such as those for the quality management system under which the product is produced, if required by the certification scheme) have been fulfilled.

NOTE 2 The certification scheme can indicate whether the evaluation is performed by the certification body, under its responsibility, or is performed prior to the application (see 7.2) for the certification process. In the latter case, the requirements of 7.4 are not applicable.

7.5 Review

7.5.1 The certification body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.

7.5.2 Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person.

7.6 Certification decision

7.6.1 The certification body shall be responsible for, and shall retain authority for, its decisions relating to certification.

7.6.2 The certification body shall assign at least one person to make the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision shall be carried out by a person or group of persons [e.g. a committee (see 5.1.4)] that has not been involved in the process for evaluation (see 7.4).

NOTE The review and the certification decision can be completed concurrently by the same person or group of persons.

7.6.3 The person(s) [excluding members of committees (see 5.1.4)] assigned by the certification body to make a certification decision shall be employed by, or shall be under contract with, one of the following:

— the certification body (see 6.1);

— an entity under the organizational control of the certification body (see 7.6.4).

7.6.4 A certification body's organizational control shall be one of the following:

— whole or majority ownership of another entity by the certification body;

— majority participation by the certification body on the board of directors of another entity;

— a documented authority by the certification body over another entity in a network of legal entities (in which the certification body resides), linked by ownership or board of director control.

NOTE For governmental certification bodies, other parts of the same government can be considered to be "linked by ownership" to the certification body.

7.6.5 The persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements of this International Standard as persons employed by, or under contract with, the certification body.

7.6.6 The certification body shall notify the client of a decision not to grant certification, and shall identify the reasons for the decision.

NOTE If the client expresses interest in continuing the certification process, the certification body can resume the process for evaluation from 7.4.

7.7 Certification documentation

7.7.1 The certification body shall provide the client with formal certification documentation that clearly conveys, or permits identification of the following:

a) the name and address of the certification body;

b) the date certification is granted (the date shall not precede the date on which the certification decision was completed);

c) the name and address of the client;

d) the scope of certification (see 3.10);

NOTE Where the standard(s) or other normative document(s) (see 7.1.2) to which conformity is being certified include reference to other standards or normative documents, these do not need to be included in the formal certification documentation.

e) the term or expiry date of certification, if certification expires after an established period;

f) any other information required by the certification scheme.

7.7.2 The formal certification documentation shall include the signature or other defined authorization of the person(s) of the certification body assigned such responsibility.

NOTE The name and title of an individual whose agreement to be responsible for certification documentation is on record at the certification body is an example of a "defined authorization" other than a signature.

7.7.3 Formal certification documentation (see 7.7) shall only be issued after, or concurrent with, the following:

a) the decision to grant or extend the scope of certification (see 7.6.1) has been made;

b) certification requirements have been fulfilled;

c) the certification agreement (see 4.1.2) has been completed/signed.

7.8 Directory of certified products

The certification body shall maintain information on certified products which contains at least the following:

a) identification of the product;

b) the standard(s) and other normative document(s) to which conformity has been certified;

c) identification of the client.

The parts of this information that need to be published or made available upon request in a directory (through publications, electronic media or other means) are stipulated by the relevant scheme(s). As a minimum, the certification body shall provide information, upon request, about the validity of a given certification.

NOTE Where the certification body provides the information to a scheme, the scheme directory would satisfy this requirement.

7.9 Surveillance

7.9.1 If surveillance is required by the certification scheme, or as specified in 7.9.3 or 7.9.4, the certification body shall initiate surveillance of the product(s) covered by the certification decision in accordance with the certification scheme.

NOTE 1 ISO/IEC 17067 provides examples of surveillance activities in certification schemes.

NOTE 2 The criteria and process for surveillance activities are defined by each certification scheme.

7.9.2 When surveillance utilizes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

7.9.3 When continuing use of a certification mark is authorized for placement on a product (or its packaging, or information accompanying it) (for process or service, see 7.9.4) of a type which has been certified, surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.

7.9.4 When continuing use of a certification mark is authorized for a process or service, surveillance shall be established and shall include periodic surveillance activities to ensure ongoing validity of the demonstration of fulfilment of process or service requirements.

7.10 Changes affecting certification

7.10.1 When the certification scheme introduces new or revised requirements that affect the client, the certification body shall ensure these changes are communicated to all clients. The certification body shall verify the implementation of the changes by its clients and shall take actions required by the scheme.

NOTE Contractual arrangements with clients can be necessary to ensure implementation of these requirements. A model of a license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is given in ISO/IEC Guide 28:2004, Annex E.

7.10.2 The certification body shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.

NOTE Changes affecting certification can include new information related to the fulfilment of certification requirements obtained by the certification body after certification has been established.

7.10.3 The actions to implement changes affecting certification shall include, if required, the following:

— evaluation (see 7.4);

— review (see 7.5);

— decision (see 7.6);

— issuance of revised formal certification documentation (see 7.7) to extend or reduce the scope of certification;

— issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme).

These actions shall be completed in accordance with applicable parts of 7.4, 7.5, 7.6, 7.7 and 7.8. Records (see 7.12) shall include the rationale for excluding any of the above activities (e.g. when a certification requirement that is not a product requirement changes, and no evaluation, review or decision activities are necessary).

7.11 Termination, reduction, suspension or withdrawal of certification

7.11.1 When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, the certification body shall consider and decide upon the appropriate action.

NOTE Appropriate action can include the following:

a) continuation of certification under conditions specified by the certification body (e.g. increased surveillance);

b) reduction in the scope of certification to remove nonconforming product variants;

c) suspension of the certification pending remedial action by the client;

d) withdrawal of the certification.

7.11.2 When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

7.11.3 If certification is terminated (by request of the client), suspended or withdrawn, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

7.11.4 If certification is suspended, the certification body shall assign one or more persons to formulate and communicate the following to the client:

— actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;

— any other actions required by the certification scheme.

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications (see 6.1).

7.11.5 Any evaluations, reviews or decisions needed to resolve the suspension, or that are required by the certification scheme, shall be completed in accordance with the applicable parts of 7.4, 7.5, 7.6, 7.7.3, 7.9 and 7.11.3.

7.11.6 If certification is reinstated after suspension, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

7.12 Records

7.12.1 The certification body shall retain records to demonstrate that all certification process requirements (those in this International Standard and those of the certification scheme) have been effectively fulfilled (see also 8.4).

7.12.2 The certification body shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained (see also 4.5).

7.12.3 If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained at least for the current and the previous cycle. Otherwise, records shall be retained for a period defined by the certification body.

NOTE In defining retention times, legal circumstances and recognition arrangements can be considered.

7.13 Complaints and appeals

7.13.1 The certification body shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The certification body shall record and track complaints and appeals, as well as actions undertaken to resolve them.

7.13.2 Upon receipt of a complaint or appeal, the certification body shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it.

7.13.3 The certification body shall acknowledge receipt of a formal complaint or appeal.

7.13.4 The certification body shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

7.13.5 The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal.

7.13.6 To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy (see 3.2) for a client, or been employed by a client, shall not be used by the certification body to review or approve the resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.

7.13.7 Whenever possible, the certification body shall give formal notice of the outcome and the end of the complaint process to the complainant.

7.13.8 The certification body shall give formal notice of the outcome and the end of the appeal process to the appellant.

7.13.9 The certification body shall take any subsequent action needed to resolve the complaint or appeal.

8 Management system requirements

8.1 Options

8.1.1 General

The certification body shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B.

8.1.2 Option A

The management system of the certification body shall address the following:

— general management system documentation (e.g. manual, policies, definition of responsibilities, see 8.2);

— control of documents (see 8.3);

— control of records (see 8.4);

— management review (see 8.5);

— internal audit (see 8.6);

— corrective actions (see 8.7);

— preventive actions (see 8.8).

8.1.3 Option B

A certification body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of this International Standard, fulfils the management system clause requirements (see 8.2 to 8.8).

NOTE Option B is included to enable a certification body which operates a management system in accordance with ISO 9001 to use that system to demonstrate fulfilment of the management system requirements in 8.2 to 8.8 of this International Standard. Option B does not require that the certification body's management system is certified to ISO 9001.

8.2 General management system documentation (Option A)

8.2.1 The certification body's top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and the certification scheme and shall ensure the policies and objectives are acknowledged and implemented at all levels of the certification body’s organization.

8.2.2 The certification body's top management shall provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of this International Standard.

8.2.3 The certification body's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:

a) ensuring that processes and procedures needed for the management system are established, implemented and maintained;

b) reporting to top management on the performance of the management system and any need for improvement.

8.2.4 All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard shall be included, referenced, or linked to documentation of the management system.

8.2.5 All personnel involved in certification activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of documents (Option A)

8.3.1 The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard.

8.3.2 The procedures shall define the controls needed to:

a) approve documents for adequacy prior to issue;

b) review and update (as necessary) and re-approve documents;

c) ensure that changes and the current revision status of documents are identified;

d) ensure that relevant versions of applicable documents are available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin are identified and their distribution controlled;

g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

NOTE Documentation can be in any form or type of medium.

8.4 Control of records (Option A)

8.4.1 The certification body shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard.

8.4.2 The certification body shall establish procedures for retaining records (see 7.12) for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

8.5 Management review (Option A)

8.5.1 General

8.5.1.1 The certification body's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard.

8.5.1.2 These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments shall be completed within a 12-month time frame. Records of reviews shall be maintained.

8.5.2 Review inputs

The input to the management review shall include information related to the following:

a) results of internal and external audits;

b) feedback from clients and interested parties related to the fulfilment of this International Standard;

NOTE Interested parties can include scheme owners.

c) feedback from the mechanism for safeguarding impartiality;

d) the status of preventive and corrective actions;

e) follow-up actions from previous management reviews;

f) the fulfilment of objectives;

g) changes that could affect the management system;

h) appeals and complaints.

8.5.3 Review outputs

The outputs from the management review shall include decisions and actions related to the following:

a) improvement of the effectiveness of the management system and its processes;

b) improvement of the certification body related to the fulfilment of this International Standard;

c) resource needs.

8.6 Internal audits (Option A)

8.6.1 The certification body shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained.

NOTE ISO 19011 provides guidelines for conducting internal audits.

8.6.2 An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

8.6.3 Internal audits shall normally be performed at least once every 12 months, or completed within a 12-month time frame for segmented (or rolling) internal audits. A documented decision-making process shall be followed to change (reduce or restore) the frequency of internal audits or the time frame in which internal audits shall be completed. Such changes shall be based on the relative stability and ongoing effectiveness of the management system. Records of decisions to change the frequency of internal audits, or the time frame in which they will be completed, including the rationale for the change, shall be maintained.

8.6.4 The certification body shall ensure that:

a) internal audits are conducted by personnel knowledgeable in certification, auditing and the requirements of this International Standard;

b) auditors do not audit their own work;

c) personnel responsible for the area audited are informed of the outcome of the audit;

d) any actions resulting from internal audits are taken in a timely and appropriate manner;

e) any opportunities for improvement are identified.

8.7 Corrective actions (Option A)

8.7.1 The certification body shall establish procedures for identification and management of nonconformities in its operations.

8.7.2 The certification body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence.

8.7.3 Corrective actions shall be appropriate to the impact of the problems encountered.

8.7.4 The procedures for corrective actions shall define requirements for the following:

a) identifying nonconformities (e.g. from complaints and internal audits);

b) determining the causes of nonconformity;

c) correcting nonconformities;

d) evaluating the need for actions to ensure that nonconformities do not recur;

e) determining and implementing the actions needed in a timely manner;

f) recording the results of actions taken;

g) reviewing the effectiveness of corrective actions.

8.8 Preventive actions (Option A)

8.8.1 The certification body shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities.

8.8.2 Preventive actions taken shall be appropriate to the probable impact of the potential problems.

8.8.3 The procedures for preventive actions shall define requirements for the following:

a) identifying potential nonconformities and their causes;

b) evaluating the need for action to prevent the occurrence of nonconformities;

c) determining and implementing the action needed;

d) recording the results of actions taken;

e) reviewing the effectiveness of the preventive actions taken.

NOTE The procedures for corrective and preventive actions do not necessarily have to be separate.

Annex A
(informative)

Principles for product certification bodies and their certification activities

A.1 General

A.1.1 The overall aim of certification is to give confidence to all interested parties that a product fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to the following:

a) the clients of the certification bodies;

b) the customers of the organizations whose products are certified;

c) governmental authorities;

d) non-governmental organizations;

e) consumers and other members of the public.

A.1.2 The principles for inspiring confidence are those specified in Clauses A.2 to A.6.

A.2 Impartiality

A.2.1 It is necessary for certification bodies and their personnel to be impartial, and to be perceived as impartial, in order to give confidence in their activities and their outcomes.

A.2.2 Risks to impartiality include bias that may arise from the following:

a) self-interest (e.g. overdependence on a contract for service or the fees, or fear of losing the client or fear of becoming unemployed, to an extent that adversely affects impartiality in carrying out conformity assessment activities);

b) self-review (e.g. performing a conformity assessment activity in which the certification body evaluates the results of other services it has already provided, such as consultancy);

c) advocacy (e.g. a certification body or its personnel acting in support of, or in opposition to, a given company which is at the same time its client);

d) over-familiarity, i.e. risks that arise from a certification body or its personnel being overly familiar or too trusting, instead of seeking evidence of conformity (in the product certification context, this risk is more difficult to manage because the need for personnel with very specific expertise often limits the availability of qualified personnel);

e) intimidation (e.g. the certification body or its personnel can be deterred from acting impartiality by risks from, or fear of, a client or other interested party);

f) competition (e.g. between the client and a contracted person).

A.3 Competence

The competence of the personnel supported by the management system of the certification body is necessary in order to deliver certification that provides confidence.

A.4 Confidentiality and openness

A.4.1 General

Managing the balance between requirements related to confidentiality (see A.4.2) and openness (see A.4.3) affects the trust of stakeholders and their perception of value in the conformity assessment activities being performed.

A.4.2 Confidentiality

To gain access to the information needed to conduct effective conformity assessment activities, the certification body needs to provide confidence that confidential information will not be disclosed.

All organizations and personnel have the right to ensure the protection of any proprietary information that they provide, unless the law or the certification scheme that has been applied for requires disclosure of proprietary information (see 4.5).

A.4.3 Openness

A certification body needs to provide access to, and disclosure of, appropriate and timely information about its evaluation and certification processes, as well as about the certification status of any product (i.e. granting, maintaining, extending or reducing the scope of, suspending, withdrawing or refusing certification), in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.

A.4.4 Access to information

Any information held by the certification body on a product that is the subject of an evaluation and/or certification should be made accessible, upon request, to the person or organization that contracted the certification body to undertake the certification activity.

A.5 Responsiveness to complaints and appeals

The effective resolution of complaints and appeals is an important means of protection for the certification body, its clients and other users of conformity assessment against errors, omissions or unreasonable behaviour. Confidence in conformity assessment activities is safeguarded when complaints and appeals are processed appropriately.

A.6 Responsibility

A.6.1 The client, not the certification body, has the responsibility of fulfilling the certification requirements.

A.6.2 The certification body has the responsibility to obtain sufficient objective evidence upon which to base a certification decision. Based on a review of the evidence, it makes a decision to grant certification if there is sufficient evidence of conformity, or a decision not to grant certification if there is not sufficient evidence of conformity, or a decision not to maintain certification.

Annex B
(informative)

Application of this International Standard for processes and services

B.1 Explanations of how to apply this International Standard to the certification of processes

When applying this International Standard to the certification of processes:

— replace “product(s)” with “process(es)”;

— replace “production” with “operation”;

— replace “produced” with “operated”;

— replace “producing” with “operating”.

B.2 Explanations of how to apply this International Standard to the certification of services

When applying this International Standard to the certification of services:

— replace “product(s)” with “service(s)”;

— replace “production” with “provision”;

— replace “produced” with “provided”;

— replace “producing” with “providing”.

Bibliography

[1] ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

[2] ISO 9001, *Quality management systems — Requirements*

[3] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*

[4] ISO/PAS 17001, *Conformity assessment — Impartiality — Principles and requirements*

[5] ISO/PAS 17002, *Conformity assessment — Confidentiality — Principles and requirements*

[6] ISO/PAS 17003, *Conformity assessment — Complaints and appeals — Principles and requirements*

[7] ISO/PAS 17004, *Conformity assessment — Disclosure of information — Principles and requirements*

[8] ISO/PAS 17005, *Conformity assessment — Use of management systems — Principles and requirements*

[9] ISO/IEC 17007, *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment*

[10] ISO/IEC 17030, *Conformity assessment — General requirements for third-party marks of conformity*

[11] ISO/IEC 17067[1)], *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

[12] ISO 19011[2)], *Guidelines for auditing management systems*

[13] ISO 31000, *Risk management — Principles and guidelines*

[14] ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems*

[15] ISO Guide 27, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

[16] ISO/IEC Guide 28:2004, *Conformity assessment — Guidance on a third-party certification system for products*

[17] ISO/IEC Guide 53, *Conformity assessment — Guidance on the use of an organization's quality management system in product certification*

[18] IAF GD 5, *IAF Guidance on the Application of ISO/IEC Guide 65:1996*

1) Revision of ISO/IEC Guide 67:2004.

2) References in this International Standard to the relevant guidance in ISO 19011 apply to the auditing of all other types of management systems.

ICS 03.120.20

Price based on 27 pages

BSI Standards Publication

Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes (ISO/IEC 17067:2013)

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN ISO/IEC 17067:2013. It supersedes PD ISO/IEC Guide 67:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CAS/1, Conformity assessment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

ISBN 978 0 580 73380 2

ICS 03.120.20

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2013.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO/IEC 17067

August 2013

ICS 03.120.20

English version

Conformity assessment - Fundamentals of product certification and guidelines for product certification schemes (ISO/IEC 17067:2013)

Évaluation de la conformité - Éléments fondamentaux de la certification de produits et lignes directrices pour les programmes de certification de produits (ISO/IEC 17067:2013)

Konformitätsbewertung - Grundlagen der Produktzertifizierung und Leitlinien für Produktzertifizierungsprogramme (ISO/IEC 17067:2013)

This European Standard was approved by CEN on 12 July 2013.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO/IEC 17067:2013 E

Foreword

This document (EN ISO/IEC 17067:2013) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/TC 1 “Criteria for conformity assessment bodies” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2014, and conflicting national standards shall be withdrawn at the latest by February 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEC 17067:2013 has been approved by CEN as EN ISO/IEC 17067:2013 without any modification.

Contents

Page

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft International Standards are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 17067 was prepared by the *ISO Committee on conformity assessment* (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17067 cancels and replaces ISO/IEC Guide 67:2004, which has been technically revised.

The following major changes have been made compared with ISO/IEC Guide 67:2004:

— a new Clause 6 has been added, providing guidelines on setting up and operating a product certification scheme;

— some of the text originally in the main body of ISO/IEC Guide 67 has been moved to the Introduction;

— the functional approach to conformity assessment has been emphasised;

— Table 1 has been extended to reflect the functional approach;

— explicit provision has been made for type and batch certification schemes;

— references to ISO/IEC 17065:2012 have replaced references to ISO/IEC Guide 65:1996;

— the text has been made more concise in places.

Introduction

This International Standard describes the fundamentals of product certification and provides guidelines for product certification schemes. In this International Standard references to the term "product" can also be read to mean "services" or "processes".

As products are designed, produced, distributed, used and ultimately disposed of, they can give rise to concerns with purchasers, users and society in general. Such concerns could relate to safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions.

Generally, these concerns are addressed by specifying the required product attributes in a normative document such as a standard.

The supplier of the product then has the task of demonstrating that the product conforms to the requirements of the normative document.

It might be sufficient for the supplier to assess and declare its product's conformity, but in other cases the user or a regulatory authority might require that conformity be assessed by a competent and impartial third party.

Assessment and impartial third party attestation that fulfilment of specified requirements has been demonstrated for the product is referred to as product certification.

This International Standard outlines how schemes for product certification can be structured and managed. It identifies common assessment techniques that are used as a basis for product certification, such as product testing, inspection and auditing.

This International Standard is intended for use by those involved with product certification, particularly those who are, or who are considering becoming, product certification scheme owners. Product certification scheme owners can include:

a) product certification bodies;

b) government and regulators;

c) purchasing agencies;

d) non-government organizations;

e) industry and retail associations; and

f) consumer organizations.

This International Standard provides only guidance and does not contain requirements. It is compatible with ISO/IEC 17065, which specifies requirements for product certification bodies.

In this International Standard, the following verbal forms are used:

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

The modal verb "shall", which indicates a requirement, is not used because this International Standard only provides guidelines.

Further details can be found in the ISO/IEC Directives, Part 2.

Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

1 Scope

This International Standard describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.

It is intended for use by all with an interest in product certification, and especially by certification scheme owners.

NOTE 1 In this International Standard the term "product" can also be read as "process" or "service", except in those instances where separate provisions are stated for "processes" or "services". Definitions of product, process and service are given in ISO/IEC 17065.

NOTE 2 The certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000) carried out by product certification bodies. The requirements for product certification bodies are specified in ISO/IEC 17065.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17065 and the following apply.

3.1
certification system
rules, procedures and management for carrying out certification

[SOURCE: ISO/IEC 17000:2004, 2.7, modified]

3.2
certification scheme
certification system (3.1) related to specified products, to which the same specified requirements, specific rules and procedures apply

Note 1 to entry: The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

[SOURCE: ISO/IEC 17065:2012, 3.9, modified]

3.3
scheme owner
person or organization responsible for developing and maintaining a specific *certification scheme* (3.2)

Note 1 to entry: The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

[SOURCE: , 3.11]

4 Product certification

4.1 Concept of product certification

4.1.1 Product certification is the provision of assessment and impartial third-party attestation that fulfilment of specified requirements has been demonstrated. Product certification is carried out by product certification bodies which should conform to ISO/IEC 17065. Specified requirements for products are generally contained in standards or other normative documents.

4.1.2 Product certification is an established conformity assessment activity that provides confidence to consumers, regulators, industry and other interested parties that products conform to specified requirements, including for example product performance, safety, interoperability and sustainability.

4.1.3 Product certification can facilitate trade, market access, fair competition and consumer acceptance of products on a national, regional and international level.

4.2 Objectives of product certification

4.2.1 The fundamental objectives of product certification are:

a) to address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of specified requirements;

b) to allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body.

4.2.2 Product certification should provide the following:

— confidence for those with an interest in fulfilment of requirements, and

— sufficient value so that suppliers can effectively market products.

5 Product certification schemes

5.1 Basics

5.1.1 Product certification schemes should implement the functional approach as described in ISO/IEC 17000:2004, Annex A. The functions are:

— **selection**, which includes planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function;

— **determination**, which may include conformity assessment activities such as testing, measuring, inspection, design appraisal, assessment of services and processes and auditing to provide information regarding the product requirements as input to the review and attestation functions;

— **review**, which means verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of specified requirements (see ISO/IEC 17000:2004, 5.1);

— **decision** on certification;

— **attestation**, which means issue of a statement of conformity, based on a decision following review, that fulfilment of specified requirements has been demonstrated (see ISO/IEC 17000:2004, 5.2);

— **surveillance** (where needed), which means systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (see ISO/IEC 17000:2004, 6.1).

NOTE 1 Further information about the functions is given in ISO/IEC 17000.

NOTE 2 In ISO/IEC 17065, the functions of "selection" and "determination" have been combined and are referred to as "evaluation".

NOTE 3 In ISO/IEC 17065, the function of "attestation" is related to the subclause on "certification documentation" (see ISO/IEC 17065:2012, 7.7).

5.1.2 Whenever product certification is performed, a certification scheme (see 3.2) is in place.

5.2 Functions and activities in product certification schemes

5.2.1 Product certification schemes are developed by defining specific activities for each of the applicable functions described in 5.1.1. Table 1 shows how to build a product certification scheme by using these functions, and outlines some of the combinations of activities in use in the wide range of fields where product certification is employed. The types of product certification schemes in Table 1 are further described in 5.3.

5.2.2 Clause 6 describes the process for deciding which activities to use for a given situation and the factors to be taken into account in making the decision.

Table 1 — Building a product certification scheme

	Conformity assessment functions and activities[a] within product certification schemes	Types of product certification schemes[b]							
		1a	1b	2	3	4	5	6	*N*[c,d]
I	**Selection**, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II	**Determination of characteristics**, as applicable, by: a) testing b) inspection c) design appraisal d) assessment of services or processes e) other determination activities, e.g. verification	x	x	x	x	x	x	x	x
III	**Review** Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	x
IV	**Decision on certification** Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V	**Attestation, licensing**								
	a) issuing a certificate of conformity or other statement of conformity (attestation)	x	x	x	x	x	x	x	x
	b) granting the right to use certificates or other statements of conformity	x	x	x	x	x	x	x	
	c) issuing a certificate of conformity for a batch of products		x						
	d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.		x	x	x	x	x	x	
VI	**Surveillance**, as applicable (see 5.3.4 to 5.3.8), by:								
	a) testing or inspection of samples from the open market			x		x	x		
	b) testing or inspection of samples from the factory				x	x	x		
	c) assessment of the production, the delivery of the service or the operation of the process				x	x	x	x	
	d) management system audits combined with random tests or inspections						x	x	

[a] Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.

[b] An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.

[c] A product certification scheme includes at least the activities I, II, III, IV and V a).

[d] The symbol *N* has been added to show an undefined number of possible other schemes, which can be based on different activities.

5.3 Types of product certification schemes

5.3.1 General

The examples given in 5.3.2 to 5.3.8 do not represent all possible types of product certification schemes. They may be used with many types of requirements and may use a wide variety of statements of conformity (see ISO/IEC 17000:2004, 5.2, Note 1). All types of product certification schemes involve selection, determination, review, decision and attestation. One or more determination activities should be selected from among those in Table 1, taking into account the product and the specified requirements. The types of schemes referred to in Table 1 differ according to which surveillance activities (if applicable)

are carried out. For scheme types 1a and 1b, no surveillance is required since the attestation relates only to the product items which have been subjected to the determination activities. For the other scheme types, 5.3.4 to 5.3.8 outline the way in which the different surveillance activities can be used and the circumstances to which they could be applicable.

5.3.2 Scheme type 1a

In this scheme, one or more samples of the product are subjected to the determination activities. A certificate of conformity or other statement of conformity (e.g. a letter) is issued for the product type, the characteristics of which are detailed in the certificate or a document referred to in the certificate. Subsequent production items are not covered by the certification body's attestation of conformity.

The samples are representative of subsequent production items which could be referred to by the manufacturer as being manufactured in accordance with the certified type.

The certification body may grant to the manufacturer the right to use the type certificate or other statement of conformity (e.g. letter) as a basis for the manufacturer to declare that subsequent production items conform to the specified requirements.

5.3.3 Scheme type 1b

This scheme type involves the certification of a whole batch of products, following selection and determination as specified in the scheme. The proportion to be tested, which can include testing of all the units in the batch (100% testing), would be based, for example, on the homogeneity of the items in the batch and the application of a sampling plan, where appropriate. If the outcome of the determination, review and decision is positive, all items in the batch may be described as certified and may have a mark of conformity affixed, if that is included in the scheme.

5.3.4 Scheme type 2

The surveillance part of this scheme involves periodically taking samples of the product from the market and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements.

While this scheme may identify the impact of the distribution channel on conformity, the resources it requires can be extensive. Also, when significant nonconformities are found, effective corrective measures may be limited since the product has already been distributed to the market.

5.3.5 Scheme type 3

The surveillance part of this scheme involves periodically taking samples of the product from the point of production and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme does not provide any indication of the impact the distribution channel plays on conformity. When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution occurs.

5.3.6 Scheme type 4

The surveillance part of this scheme allows for the choice between periodically taking samples of the product from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme can both indicate the impact of the distribution channel on conformity and provide a pre-market mechanism to identify and resolve serious nonconformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.

5.3.7 Scheme type 5

The surveillance part of this scheme allows for the choice between periodically taking samples of the product either from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process, or audit of the management system, or both. The extent to which the four surveillance activities are conducted may be varied for a given situation, as defined in the scheme. If the surveillance includes audit of the management system, an initial audit of the management system will be needed.

5.3.8 Scheme type 6

This scheme is mainly applicable to certification of services and processes.

Although services are considered as being generally intangible, the determination activities are not limited to the evaluation of intangible elements (e.g. effectiveness of an organization's procedures, delays and responsiveness of the management). In some situations, the tangible elements of a service can support the evidence of conformity indicated by the assessment of processes, resources and controls involved. For example, inspection of the cleanliness of vehicles for the quality of public transportation.

As far as processes are concerned, the situation is very similar. For example, the determination activities for welding processes can include testing and inspection of samples of the resultant welds, if applicable.

For both services and processes, the surveillance part of this scheme should include periodic audits of the management system and periodic assessment of the service or process.

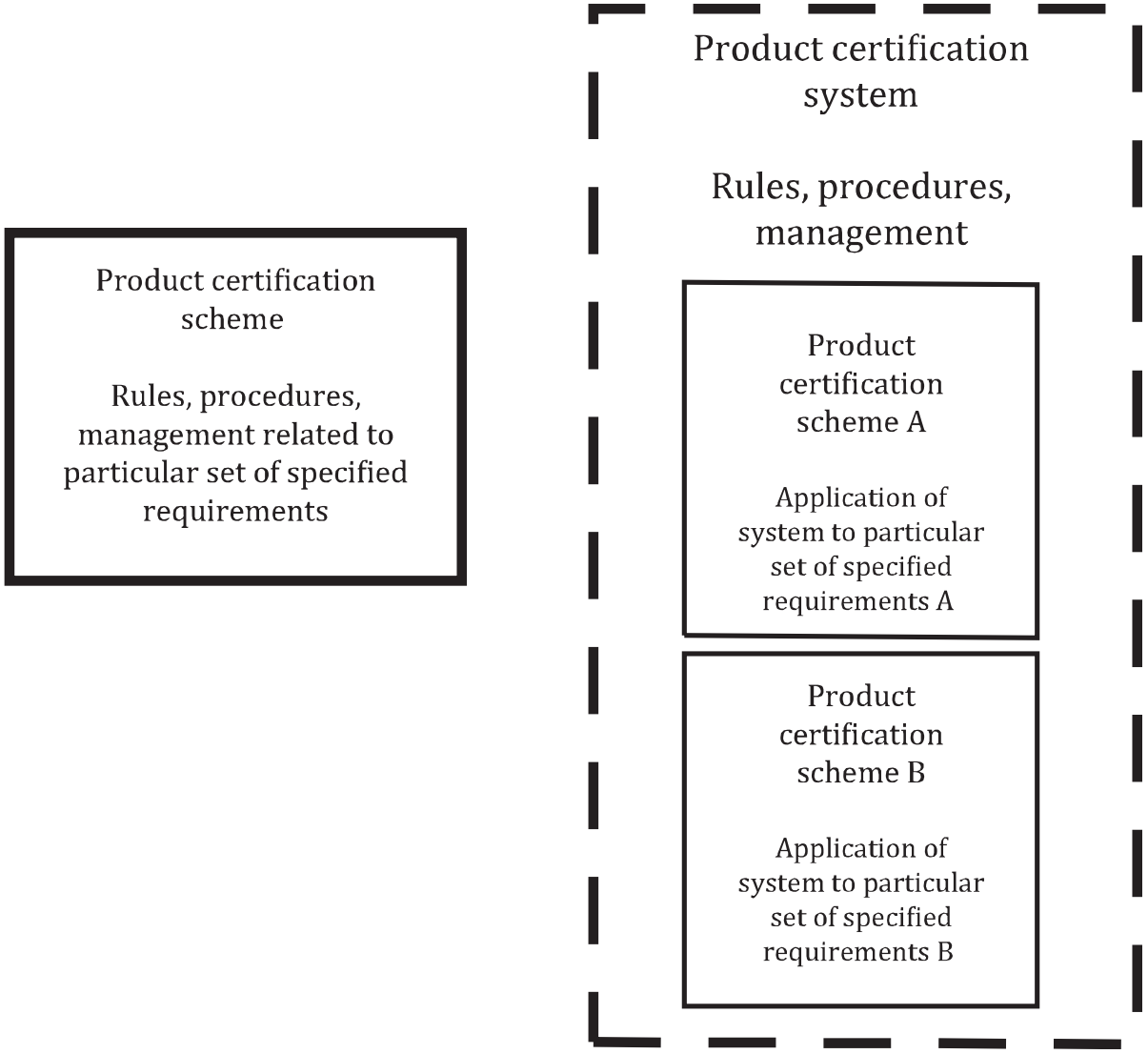
6 Development and operation of a product certification scheme

6.1 General

This clause provides guidelines on how to develop and operate a product certification scheme. It is particularly relevant to those persons and organizations that are considering the establishment of a scheme or acting as a stakeholder (e.g. manufacturer, service provider, certification body, customer or public authority).

6.2 Relationship between product certification scheme and product certification system

The product certification scheme will use defined rules, procedures and management, which could be unique to the scheme or could be defined in a product certification system applicable to a number of schemes. It is always necessary to have a product certification scheme, but only necessary to separately define a product certification system if the same rules, procedures and management are to be used for more than one scheme. Figure 1 illustrates the relationship between a product certification scheme and a product certification system.



a) Unique product certification scheme

b) Product certification system relating to several schemes

Figure 1 — Relationship between product certification scheme and product certification system

6.3 Scheme owner

6.3.1 The following main types of scheme owners can be identified:

a) certification bodies which develop a product certification scheme for the sole use of their clients;

b) organizations such as a regulatory body or a trade association not being a certification body, which develop a product certification scheme in which one or more certification bodies participate.

NOTE A group of certification bodies, perhaps in different countries, can together set up a certification scheme. In that case, it would be necessary for the certification bodies, as joint owners of the scheme, to create a management structure so that the scheme could be operated effectively by all participating certification bodies.

6.3.2 If a scheme owner operates several schemes, the scheme owner may combine common procedures and management into a product certification system. In that case, the scheme owner would become the system owner and would be responsible for the management of the system and the schemes operating within it.

6.3.3 The scheme owner should be a legal entity.

NOTE A governmental scheme owner is deemed to be a legal entity on the basis of its governmental status.

6.3.4 The scheme owner should be able to take on full responsibility for the objectives, the content and the integrity of the scheme.

6.3.5 The scheme owner should maintain the scheme and provide guidance when required.

6.3.6 The scheme owner should set up a structure for the operation and management of the scheme.

6.3.7 The scheme owner should document the content of the scheme.

6.3.8 The scheme owner should ensure that the scheme is developed by persons competent in both technical and conformity assessment aspects.

6.3.9 The scheme owner should make arrangements to protect the confidentiality of information provided by the parties involved in the scheme.

6.3.10 The scheme owner should evaluate and manage the risks/liabilities arising from its activities.

NOTE Evaluating risks does not imply risk assessments in accordance with ISO 31000.

6.3.11 The scheme owner should have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities. Arrangements should be appropriate e.g. for the range of activities and schemes undertaken and in the geographic regions in which the scheme operates.

6.3.12 The scheme owner should have the financial stability and resources required for it to fulfil its role in the operation of the scheme.

6.4 Development of product certification schemes

6.4.1 Product certification schemes can be developed for different purposes. Such purposes may include schemes established by regulators to achieve health, safety or environmental outcomes. Other schemes may have the purpose of assisting clients and consumers to differentiate products in the market place and make informed purchasing decisions.

6.4.2 Irrespective of the purpose, scheme owners should understand the assumptions, influences and consequences involved in establishing, operating and maintaining a scheme on an ongoing basis.

6.4.3 In developing a scheme, the scheme owner should have a clear understanding of the objectives of the scheme and the assumptions that underlie the need for, and the acceptance of, the scheme. To assist in this, the scheme owner should identify stakeholders and seek their opinions and participation in scheme development.

6.4.4 Before developing the specific content of the scheme (see 6.5), fundamental scheme principles should be agreed among the stakeholders. Such principles may include:

— confirmation of the ownership,

— confirmation of the governance and decision making mechanisms that may or may not provide for direct involvement of stakeholders,

— confirmation of the underlying business and funding model, and

— providing an outline for monitoring and periodic review of the scheme.

6.4.5 Once developed, the scheme owner should ensure that information about the scheme is made publicly available to ensure transparency, understanding and acceptance. The scheme owner should ensure that the scheme is regularly reviewed, including confirmation that it is fulfilling its objectives, in accordance with a process that includes stakeholders.

6.5 Content of a scheme

6.5.1 General

A product certification scheme should specify the following elements:

a) the scope of the scheme, including the type of products covered;

b) the requirements against which the products are evaluated, by reference to standards or other normative documents; where it is necessary to elaborate upon the requirements to remove ambiguity, the explanations should be formulated by competent people and should be made available to all interested parties;

NOTE Further guidance on how to formulate specified requirements is provided in ISO/IEC 17007.

c) the selection of the activities (see Table 1) appropriate to the purpose and the scope of the scheme; as a minimum, a certification scheme should include the functions and activities I, II, III, IV and V a);

d) other requirements to be met by the client, e.g. the operation of a management system or process control activities to assure the demonstration of fulfilment of specified requirements is valid for the ongoing production of certified products;

e) the requirements for certification bodies and other conformity assessment bodies involved in the certification process; these requirements should not be in contradiction to the requirements of the applicable standards for conformity assessment bodies;

f) whether conformity assessment bodies involved in the scheme (e.g. testing laboratories, inspection bodies, product certification bodies, bodies auditing manufacturers' management systems) are to be accredited, participate in peer assessment or qualified in another manner; if the scheme is to require that conformity assessment bodies are accredited, the appropriate references should be specified, e.g. that the accreditation body is a member of a mutual recognition arrangement between accreditation bodies;

g) the methods and procedures to be used by the conformity assessment bodies and other organizations involved in the certification process, so as to assure the integrity and consistency of the outcome of the conformity assessment process;

h) the information to be supplied to the certification body by an applicant for certification;

i) the content of the statement of conformity (e.g. certificate) which unambiguously identifies the product to which it applies;

j) the conditions under which the client may use the statement of conformity or marks of conformity;

k) where marks of conformity may be used, the ownership, use and control of the marks; the requirements of ISO/IEC 17030 should be applied;

l) the resources required for the operation of the scheme, including impartiality and competence of the personnel (internal and external), the evaluation resources, and the use of subcontractors;

m) how the results of the determination (evaluation) and surveillance stages are to be reported and used by the certification body and the scheme owner;

n) the question of how non-conformities with the certification requirements, which include product requirements, are to be dealt with and resolved;

o) surveillance procedures, where surveillance is part of the scheme;

p) the criteria for access of conformity assessment bodies to the scheme and for the access of clients to the scheme;

q) content, conditions and responsibility for publication of the directory of certified products by the certification body or the scheme owner;

r) the need for, and content of, contracts, e.g. between scheme owner and certification body, scheme owner and clients, certification body and clients: the rights, responsibilities and liabilities of the various parties should be defined in contracts;

NOTE An example contract between a certification body and its clients can be found in ISO/IEC Guide 28:2004, Annex B.

s) general conditions for granting, maintaining, continuing, extending the scope of, reducing the scope of, suspending and withdrawing certification: this includes requirements for discontinuation of advertising and return of certification documents and any other action if the certification is suspended, withdrawn or terminated;

t) the way in which the clients' complaints records are to be verified if such verification is part of the scheme;

u) the way in which the clients make reference to the scheme in their publicity material;

v) retention of records by scheme owner and certification bodies.

6.5.2 Sampling

Where applicable, the scheme should define the extent to which sampling of the product to be certified is required, and on what basis such sampling should be undertaken both at the selection and surveillance stages. The scheme should define when sampling is required and who is permitted to undertake it.

NOTE Useful information on this topic is given in ISO 10576-1, ISO 2859-10, ISO 3951-1 and ISO 22514-1.

6.5.3 Acceptance of conformity assessment results

In some cases, clients might have obtained the results of determination activities, such as testing, inspection or auditing, prior to making an application for certification. In such a situation, the conformity assessment result may be from a source not within the contractual control of the certification body. The scheme should define whether and under what conditions such conformity assessment results can be considered in the certification process.

6.5.4 Outsourcing of the conformity assessment activities

If the scheme permits outsourcing (subcontracting) of conformity assessment activities such as testing, inspection or auditing, then the scheme should require these bodies to meet the applicable requirements of the relevant International Standards. For testing, it should meet the applicable requirements of ISO/IEC 17025; for inspection, it should meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it should meet the applicable requirements of ISO/IEC 17021. The scheme should state the degree to which prior agreement to outsourcing needs to be obtained from the scheme owner or the client whose products are being certified under the scheme.

6.5.5 Complaints and appeals to the scheme owner

The scheme owner should define the complaints and appeals process and who is responsible for undertaking this process.

Appeals against the decision of the certification body and complaints about the certification body should be addressed to the certification body in the first instance.

Appeals and complaints that have not been, or cannot be, resolved by the certification body can be addressed to the scheme owner.

6.5.6 Licensing and control of the mark

Where the scheme provides for the use of certificates, marks or other statements of conformity, there should be a license or other form of enforceable agreement to control such use. Licenses can include provisions related to use of the certificate, mark or other statement of conformity in communications about the certified product, and requirements to be fulfilled when certification is no longer valid. Such licenses may be between two or more of the following:

— scheme owner;

— certification body;

— client of the certification body.

6.5.7 Surveillance

If surveillance is included, the scheme should define the set of activities (see function 6 in Table 1) that make up the surveillance functions. When deciding upon the appropriate surveillance activities, the scheme owner should consider the nature of the product, the consequences and probability of non-conforming products and the frequency of the activities.

6.5.8 Non-conforming products

The scheme should define requirements that apply when a product no longer fulfils certification requirements, such as product recall or providing information to the market.

NOTE See also ISO Guide 27.

6.5.9 Reporting to the scheme owner

When reporting to the scheme owner is required, the content and frequency of reporting should be defined. Such reporting may be for the purpose of scheme improvement, for control purposes and for monitoring the extent of conformity by clients.

6.5.10 Subcontracting of the operation of the scheme

If the scheme owner subcontracts all or part of the operation of the scheme to another party, it should have a legally binding contract defining the duties and responsibilities of both parties. A governmental scheme owner can subcontract operation of the scheme by regulatory provisions.

6.5.11 Marketing

The scheme should define the policies and procedures related to marketing, including the extent to which certification bodies and clients can make reference to the scheme.

6.5.12 Fraudulent claim of certification

Actions and responsibilities for situations where certification under the scheme is being claimed fraudulently should be described.

6.6 Maintenance and improvement of a scheme

6.6.1 Review of scheme operation

The scheme owner should 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 should include provisions for ensuring that the scheme requirements are being applied in a consistent manner.

6.6.2 Changes in specified requirements

The scheme owner should 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 should 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 certification bodies, clients and, where necessary, other stakeholders.

6.6.3 Other changes to the scheme

The scheme owner should define a process for managing the implementation of other changes to the rules, procedures and management of the scheme.

6.7 Scheme documentation

The scheme owner should create, control and maintain adequate documentation for the operation, maintenance and improvement of the scheme. The documentation should specify the rules and the operating procedures of the scheme, and in particular the responsibilities for governance of the scheme.

Bibliography

[1] ISO 2859-10, *Sampling procedures for inspection by attributes — Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes*

[2] ISO 3951-1, *Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

[3] ISO 10576-1, *Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles*

[4] ISO/IEC 17007, *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment*

[5] ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

[6] ISO/IEC 17021 (all parts), *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

[7] ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

[8] ISO/IEC 17030, *Conformity assessment — General requirements for third-party marks of conformity*

[9] ISO 22514-1, *Statistical methods in process management — Capability and performance — Part 1: General principles and concepts*

[10] ISO 31000, *Risk management — Principles and guidelines*

[11] ISO Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

[12] ISO/IEC Guide 28:2004, *Conformity assessment — Guidance on a third-party certification system for products*

[13] ISO/IEC Guide 53, *Conformity assessment — Guidance on the use of an organization's quality management system in product certification*

[14] ISO/IEC Guide 68, *Arrangements for the recognition and acceptance of conformity assessment results*

Internal Auditor Training Course on ISO/IEC 17065:2012 & ISO/IEC 17067:2013

(Conformity assessment — Requirements for product certification bodies and scheme owner)

Trainer:

Engr. Syed Anwar Hossain

22-24 June 2025

Venue: Bangladesh Agricultural Research Council (BARC), Dhaka

Delegate Introduction

- Name
- Position and role within BACB
- Educational Qualifications
- Career background
- Knowledge of ISO/IEC 17065 or any ISO standards
- Personal objective for attending this course

Course Timing

09:00 to 17:00 each day

Lunch breaks: 13:00 – 14:00

Tea/coffee breaks: mid morning & mid afternoon

Course Objective

- Provide lessons learned regarding assessments to ISO/IEC 17065
  - Relationship with other ISO/IEC standards
  - Relationship with scheme requirements
  - Common Non-conformances
- Present examples of assessment application of ISOIEC 17065
- Share information on implementation

Agenda – Day 1

- Course Overview and Introduction
- Concepts and Definitions
- Introduction to ISO/IEC 17065 and related standards
- General Requirements Section 4
- Structural Requirements Section 5
- Resource Requirements Section 6
- Q & A and Wrap-up of Day 1

Agenda – Day 2

- Process Requirements Section 7
- Management System Section 8
- Application of Standards to Certification
- Certification process
- Application of ISO/IEC 17067
- Internal Audit Process as per ISO/IEC 17065 and ISO 19011
- IAF CASCO Interpretations
- Assessing certification body
- Q & A and Wrap-up of Day 2

Agenda – Day 3

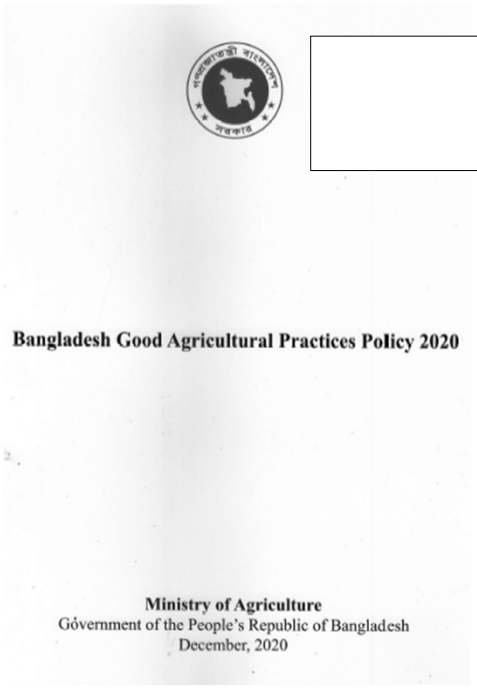
- Application of ISO/IEC 17067
- Internal Audit Process as per ISO/IEC 17065 and ISO 19011
- Assessing certification body
- Discussion on written examination
- Introduction to ISO 22000:2018
- Q & A and Wrap-up of Day 3

Background Information

The Business Standard

No agro exports without GAP certification

Abul Kashem
09 July, 2020, 12:10 pm
Last modified: 09 July, 2020, 12:50 pm



Bangladesh Good Agricultural Practices Policy 2020

Ministry of Agriculture
Government of the People's Republic of Bangladesh
December, 2020

BDS 2025:2023

Bangladesh Standard
For
Bangladesh Good Agricultural Practices
(বাংলাদেশ উত্তম কৃষি চর্চা'র মানদন্ড)

BANGLADESH STANDARDS AND TESTING INSTITUTION
MINISTRY OF INDUSTRIES
MAAN BHABAN, 116-A, TEJGAON INDUSTRIAL AREA
DHAKA-1208, BANGLADESH

BSTI

9 Distinction in Conformity Assessment

What is BDS 2025:2023?

- **A Landmark Standard:** Adopted by BSTI on December 27, 2023.
- **Primary Focus:** Good Agricultural Practices (GAP) in Bangladesh.
- **Additional Focus (Potentially):** General guidelines for exclusion of certain substances from printing ink formulations intended for use on food packages (if it shares the same BDS 2025:2023 number, which is possible for a new standard in the same year).
- **Developed by:** Bangladesh Agricultural Research Council (BARC) with consultation from various ministries and stakeholders.
- **Published in:** Bengali, to ensure wider accessibility and understanding.

10 Distinction in Conformity Assessment

National Significance

- **Goals:** Enhance human health protection, environmental conservation, product quality, and working environment.
- **Vision:** Safe, improved, and good quality agricultural produce, sustainable environment, increased social acceptance, income growth, and food & nutrition security.
- Enhance export?

Key Pillars of GAP

- Food Safety (Minimizing hazards)
- Environmental Sustainability
- Worker Health and Welfare
- Animal Welfare (where applicable)
- Traceability and Record-keeping

Key Requirements: Cultivation & Harvesting (GAP)

- **Land Management:** Site selection, soil health, and land preparation.
- **Water Usage:** Safe and responsible water sources, irrigation practices.
- **Fertilizers & Pesticides:** Judicious use, proper storage, application, and disposal of agrochemicals.
- **Seed & Planting Material:** Use of certified, disease-free materials.
- **Disease & Pest Management:** Integrated Pest Management (IPM) strategies.
- **Harvesting Practices:** Hygienic harvesting methods, proper timing.

Key Requirements: Post-Harvest Handling (GAP)

- **Cleanliness:** Maintaining hygiene of equipment, facilities, and personnel.
- **Sorting & Grading:** Proper sorting to remove damaged or contaminated produce.
- **Washing & Drying:** Safe washing practices, adequate drying to prevent spoilage.
- **Packaging Materials:** Use of food-grade, clean, and appropriate packaging.
- **Temperature Control:** Maintaining optimal temperature to preserve quality and prevent microbial growth.

Key Requirements: Storage & Transportation (GAP)

- **Storage Facilities:** Clean, well-ventilated, pest-controlled storage areas.
- **Separation:** Preventing cross-contamination between different products.
- **Temperature & Humidity Control:** Maintaining specific conditions for different produce.
- **Transportation Vehicles:** Clean, covered vehicles, proper loading and unloading.
- **Traceability:** Maintaining records of movement from farm to market.

Key Requirements: Worker Health & Safety (GAP)

- **Training:** Educating workers on hygienic practices, safe handling of chemicals, and equipment operation.
- **Personal Protective Equipment (PPE):** Providing and ensuring the use of appropriate PPE.
- **Sanitation Facilities:** Access to clean toilets and handwashing facilities.
- **First Aid:** Availability of first aid provisions.
- **Safe Working Environment:** Measures to prevent accidents and injuries.

Key Requirements: Environmental Management (GAP)

- **Waste Management:** Proper disposal of agricultural waste, including chemical containers.
- **Water Conservation:** Efficient water usage practices.
- **Biodiversity Protection:** Minimizing negative impacts on local ecosystems.
- **Soil Conservation:** Practices to prevent soil erosion and degradation.
- **Energy Efficiency:** Promoting sustainable energy use.

Benefits of BDS 2025:2023 (Agriculture)

- **Enhanced Food Safety:** Reduced risk of contamination in agricultural produce.
- **Improved Product Quality:** Better quality, freshness, and shelf-life of produce.
- **Increased Consumer Confidence:** Trust in locally grown products.
- **Environmental Protection:** Sustainable practices leading to less pollution and resource depletion.
- **Farmer Welfare:** Improved working conditions and health for agricultural workers.
- **Market Access:** Potential for greater access to domestic and international markets.

Challenges in Implementation

- **Awareness & Education:** Reaching all stakeholders, especially small farmers, with the necessary information.
- **Resource Constraints:** Financial and technical resources for adoption of new practices.
- **Infrastructure Gaps:** Need for improved storage, transportation, and testing facilities.
- **Training & Skills:** Developing a skilled workforce capable of implementing the standard.
- **Monitoring & Enforcement:** Effective mechanisms for oversight and compliance.
- **Cultural Practices:** Overcoming resistance to change in traditional farming methods.

Examples - Importance and Impact of product certification for global trade

- An unknown number of sectors, regulators, schemes and CB's run their operation under this requirements with an unknown number of certificates and products, this shows the great importance.

International level
IEC CB Scheme:
74 National Certification Bodies
382 CB Testing Laboratories
45 Satellite Laboratories
2800 Manufacturer's Testing Laboratories
70'000 CB Test Certificates issues in 2011

Europe:
New Legislation Framework (NLF) over 20 European Directives, Trade volume 1500 mrd €, about 2000 Notified Bodies
974 accredited certification bodies in Europe
(source: European Co-operation Accreditation)

Germany:
GS-mark
91 bodies

Asia

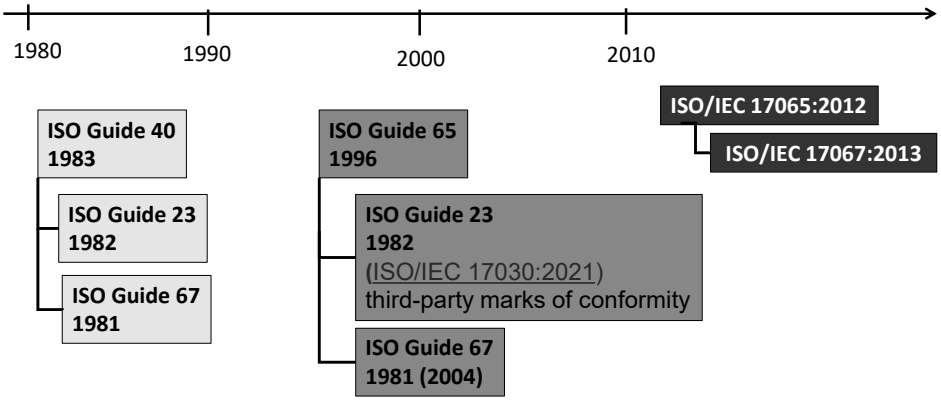
Japan
JIS-mark : 25 certification bodies
JAS-mark: 142 certification bodies
PSE-mark: 10 certification bodies
PSC-mark : 9 certification bodies
PAL : 13 certification bodies
China:
35 accredited Certification Bodies
10 Certification Bodies response for China Compulsory Certification (CCC)
50,728 companies with 280,000 certificates for CCC

New Zealand/Australia
36 certification bodies for product certification
70 product certification schemes delivered by 36 accredited bodies

Brasil
70 accredited Certification Bodies

USA
120 Accredited Certification Bodies

History of Product Certification



Purpose of Revision
ISO Guide 65 to ISO/IEC 17065

ISO IEC Guide 65

Maintain the proven parts of ISO/IEC Guide 65

Improve where necessary

ISO IEC 17065

ISO/IEC 17065

- Background
  - There has been a major change from the early 1990s to the present. Earlier, CBs were single-nation, single-legal entities, and ISO/IEC Guide 65 was based on that situation.
  - Today, CBs are embedded in multinational companies. The intent of ISO/IEC 17065 will be to apply to a range of entities – from simple companies to complex CBs.
  - WG recognized the ISO neutrality principle. Requirements had to be written to be used by anyone (auditors, scheme owners, product certification bodies). The goal was to minimize the need for IAF guidance. People can now ask for guidance from the ISO and the scheme itself rather than the IAF.

Concepts

- Principles
- Terms and Definitions
- Functional Approach
- Body versus Scheme

ISO/IEC 17065

- The primary focus in ISO/IEC 17065:
  1. The difference between the product scheme and the product CB.
  2. ISO/IEC 17065 does not restrict the role of scheme owners, because there can be no discrimination allowed on the basis of type.
- ISO/IEC 17065 does NOT mandate how CBs develop schemes.

ISO/IEC 17065

- This IS specifies requirements, the observance of which is intended to ensure that the CBs operate certification schemes in a ***competent, consistent and impartial manner***
- This IS does not set requirements for schemes and how they are developed and is not intended to restrict the role or choice of scheme owners, however scheme requirements should not contradict or exclude any of the requirements of this IS

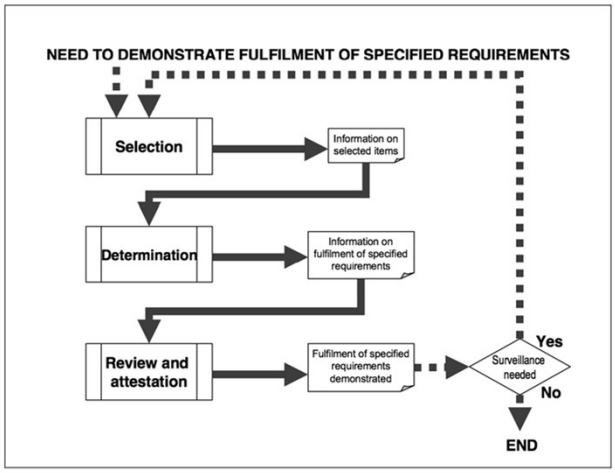
Annex A – Principles Discussion

Terms & Definitions

- ISO/IEC 17000 Plus ISOIEC 17065
  - Certification body (17065/17000)
  - Product (17065/17000)
  - Certification scheme (17065)
  - Consultancy (17065)
  - Impartiality (17065)
  - Review (17000)
  - Certification requirement (17065)
  - Product requirement (17065)

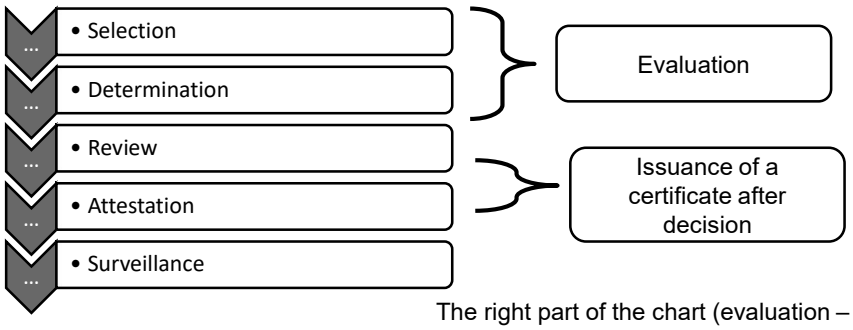
Functional Approach

Figure A.1 — A functional approach to conformity assessment



Functional Approach

The functional approach is described in ISO/IEC 17000 (left part of the chart below)



The right part of the chart (evaluation – Issuance of certificate) is the terminology used in ISO/IEC 17065

Where do you find….

- Which ISO/IEC 17065 Clause (s) address each:
  - Selection
  - Determination
  - Review
  - Attestation
  - Surveillance

Certification Scheme vs Certification Body

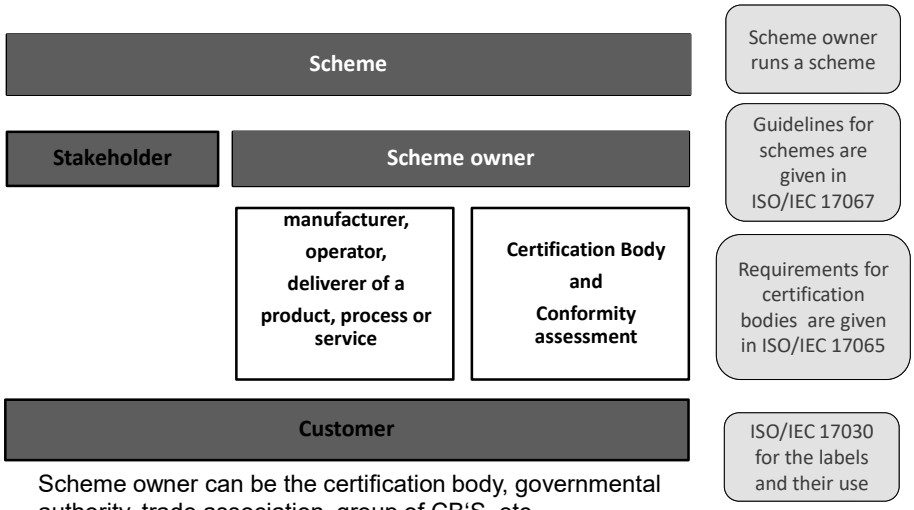
- The Scheme is all the activities and details of the process described generally by the Functional Approach
- The Body is the organization of people, facilities, equipment, etc. that carry out the scheme
  - Schemes by definition always exist
  - Bodies fill in what Schemes leave out
  - Conflicts between Schemes and ISO/IEC 17065
    - Process used by body to address differences

Schemes must be understood

Certification schemes are mandatory part of product certification (ISO/IEC17065). The requirement to operate one or more certification schemes is contained in clause 7.1.1. The term “scheme” replaces the term “system” used in ISO/IEC Guide 65

ISO/IEC 17065 does not contain detailed requirements on certification schemes. Guidelines for understanding, developing, establishing, maintaining or comparing certification schemes for products, processes and services are provided in ISO/IEC 17067 “Fundamentals of product certification and product certification schemes”

Relationship of certification body and scheme owner

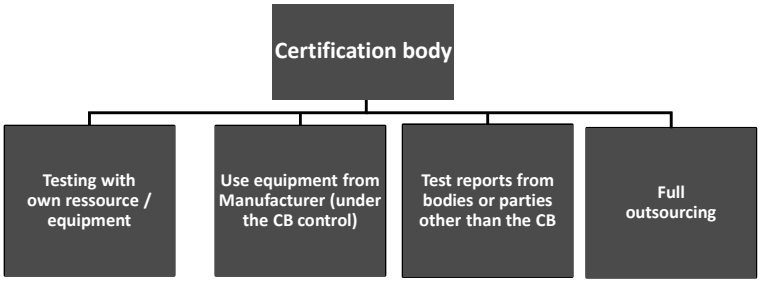


Scheme owner can be the certification body, governmental authority, trade association, group of CB'S, etc.

ISO/IEC 17065 and Related Standards

- EVALUATION ACTIVITIES – ONLY
  - Internal Resources
    - Subcontracting or contracted personnel or services following procedures of CB
  - External Resources (Outsourcing)
- Meet applicable requirements of relevant International Standard and of other documents specified by the scheme.
  - Testing = ISO/IEC 17025
  - Inspection = ISO/IEC 17020
  - Management System auditing = ISO/IEC 17021

Examples of resources used for testing, inspection and auditing



All those examples are covered in Clauses 6 of ISO/IEC 17065

Relationship with other standards

- ISO/IEC 17025 – Testing
- ISO/IEC 17020 – Inspection
- ISO/IEC 17021 – Management system auditing

What about other evaluation activities ?

Which standards from the above are applicable?

Can the CB use other standards if more relevant?

Construction analysis
Materials determination and analysis
Toxicity determination
Engineering judgment on changes
Do you know of others?

ISO/IEC 17065 Sections

1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
5. Structural requirements
6. Resource requirements
7. Process requirements
8. Management system requirements

Clause by Clause

- Section 4 General Requirements
- Section 5 Structural Requirements
- Section 6 Resource Requirements
- Section 7 Process Requirements
- Section 8 Management System Requirements

Please ask questions as we work through the standard

Important definitions

3.4 product

result of a process

NOTE 1 Four generic product categories are noted in ISO 9000:2005:

- services (e.g. transport) (see definition in 3.6);
- software (e.g. computer program, dictionary);
- hardware (e.g. engine, mechanical part);
- processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called

service, software, hardware or processed material depends on the dominant element.

NOTE 2 Products include results of natural processes, such as growth of plants and formation of other natural

resources.

NOTE 3 Adapted from ISO/IEC 17000:2004, definition 3.3.

Important definitions

3.5 process

set of interrelated or interacting activities which transforms inputs into outputs

EXAMPLES Welding engineering processes; heat treatment processes; manufacturing processes requiring

confirmation of process capability (e.g. operating or producing product within specified tolerances); food production processes; plant growth processes.

NOTE Adapted from ISO 9000:2005, definition 3.4.1.

Important definitions

3.6 service

result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

NOTE 1 Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);
- an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants).

Important definitions

3.3 evaluation

combination of the selection and determination functions of conformity assessment activities

NOTE The selection and determination functions are specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

Important definitions

3.1 client

organization or person responsible to a certification body for ensuring that **certification requirements** (3.7), including **product requirements** (3.8), are fulfilled

NOTE Whenever the term “client” is used in this International Standard, it applies to both the “applicant” and the “client”, unless otherwise specified.

Important definitions

3.2 consultancy

participation in

a) the designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or

b) the designing, implementing, operating or maintaining of a certified process or a process to be certified, or

c) the designing, implementing, providing or maintaining of a certified service or a service to be certified

NOTE In this International Standard, the term “consultancy” is used in relation to activities of certification bodies,

personnel of certification bodies and organizations related or linked to certification bodies.

Important definitions

3.7 certification requirement

specified requirement, including **product requirements** (3.8), that is fulfilled by the **client** (3.1) as a condition of establishing or maintaining certification

NOTE Certification requirements include requirements imposed on the client by the certification body [usually via the certification agreement (see 4.1.2)] to meet this International Standard, and can also include requirements imposed on the client by the certification scheme. "Certification requirements", as used in this International Standard, do not include requirements imposed on the certification body by the certification scheme.

EXAMPLE The following are certification requirements that are not product requirements:

- completing the certification agreement;
- paying fees;
- providing information about changes to the certified product;
- providing access to certified products for surveillance activities.

Important definitions

3.8 product requirement

requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme

NOTE Product requirements can be specified in normative documents such as regulations, standards and technical specifications.

Important definitions

3.9 certification scheme

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

- NOTE 1 Adapted from ISO/IEC 17000:2004, definition 2.8.
- NOTE 2 A "certification system" is a "conformity assessment system", which is defined in ISO/IEC 17000:2004, definition 2.7.
- NOTE 3 The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.
- NOTE 4 General guidance for the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

Important definitions

3.10 scope of certification

identification of

- the product(s), process(es) or service(s) for which the certification is granted,
- the applicable certification scheme, and
- the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply

Scopes of accreditation

IAF Scope	Products/ Processes covered under the scope	Description of Scheme	Standards/Regulations/ Normative document(s)
IAF Scope 01 Agriculture			
	Good Agricultural Practices Crop Base • Fruit & Vegetables • Combinable Crops • Tea • Hops	GLOBALG.A.P. Integrated Farm Assurance Ver. 5.2 - Crop Base & New Zealand G.A.P. benchmarked Scheme V6.2	General Regulations Version 5.2, Control Points and Compliance Criteria Version 5.2; NZGAP Scheme Documents V6.2

Important definitions

3.11 scheme owner

person or organization responsible for developing and maintaining a specific **certification scheme** (3.9)

NOTE The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

Important definitions

3.12 certification body

third-party conformity assessment body operating certification schemes

NOTE A certification body can be non-governmental or governmental (with or without regulatory authority).

Important definitions

3.13 impartiality

presence of objectivity

NOTE 1 Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the body.

NOTE 2 Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

What is Product certification?

Your concept?

What is product certification?

4.1.1 Product certification is the provision of assessment and impartial third-party attestation that fulfilment of specified requirements has been demonstrated. Product certification is carried out by product certification bodies which should conform to ISO/IEC 17065. Specified requirements for products are generally contained in standards or other normative documents.

- Food
- Medications
- Medical devices
- Electronic equipment
- Machinery
- Furniture
- Robotics

CE marking

- The European Union (EU) and the European Economic Area (EEA) require businesses or manufacturers seeking to sell their products in this market to have CE certifications.

BSTI Product certification

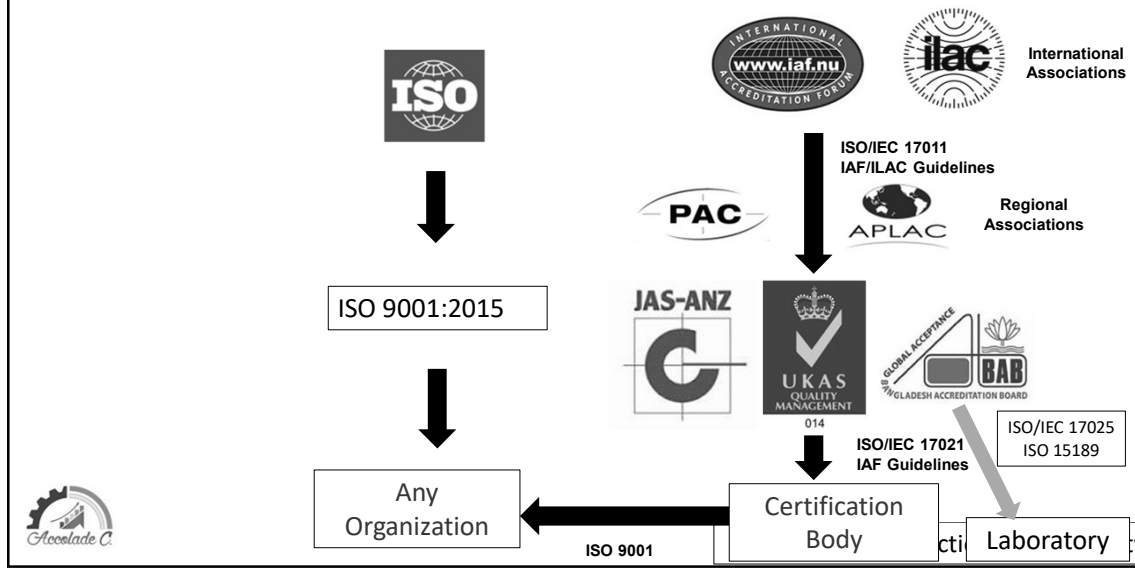
Category		Sub Category		Scope (Products/Process)	Evaluation Criteria	
					Technical Standards	Others Applicable Document
A	Food Manufacturing	A-I	Processing of Perishable animal Products	1. Pasteurized milk 2.Flavored Milk 3. Low Fat Milk	1.BDS 1702:2002 2.BDS 1471:2012 3. BDS 1866:2013	STI for each product (based on Standards)
		A-II	Processing of Perishable Plant Products	1.Fruit drinks 2.Chutney	1.BDS 1581:2015 2.BDS 521:2011	
		A-III	Processing of ambient Stable Products	1. Wafer Biscuit 2.Intermediat Protein Biscuit 3.Edible Jell 4.Fotified Soya bean Oil 5.Fortified Palm Olein 6. Fortified Edible Palm Oil 7. Fortified Edible Rice Bran Oil 8. Sweetened Condensed Filled Milk	1. BDS 1001:2010 2.BDS 1563:2011 3.BDS1801:2015 4. BDS 1769:2014 5.BDS 1774:2014 6. BDS 1770:2014 7. BDS 1886:2014 8.BDS 1780:2014	
B	Non-Food Manufacturing	B-I	Construction Materials and Building	1.Cement	1. BDS EN 197-1:2003	

EcoCert

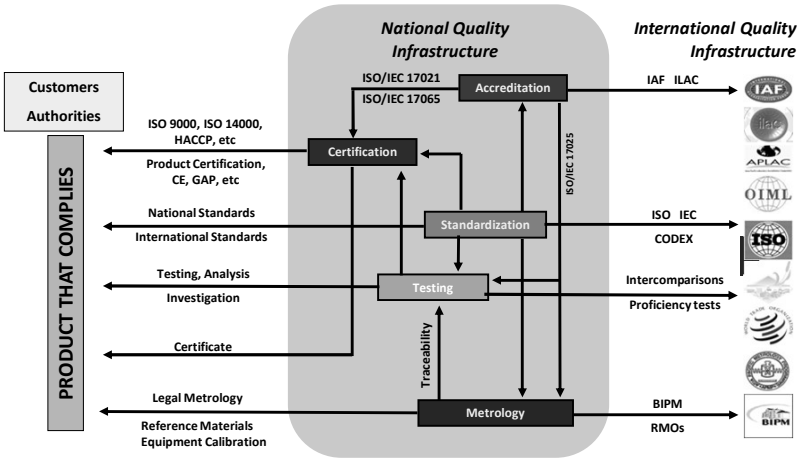
- What it is: Based in France but recognized globally, EcoCert was the first certification body to develop standards for “natural and organic cosmetics,” and they are the main certification body for such products today.

Introduction to standardization

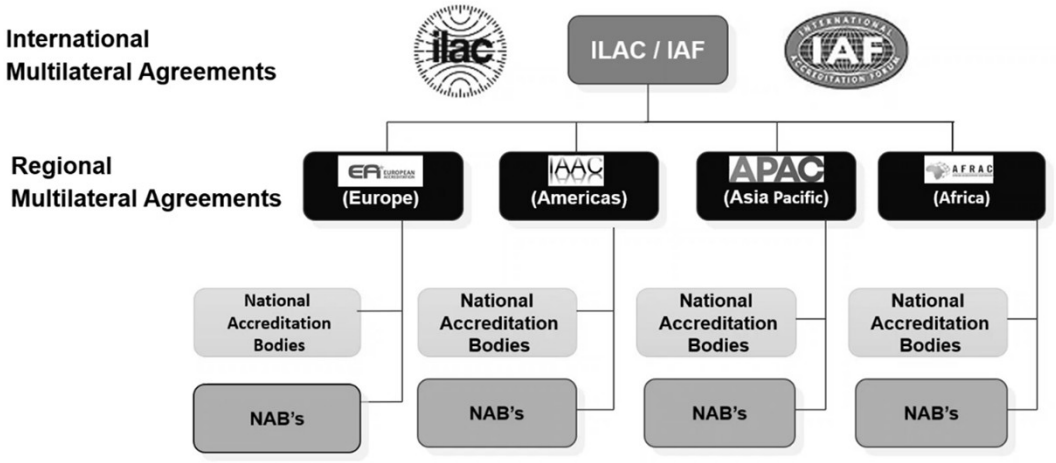
Accreditation/ Certification Process



National Quality Infrastructure



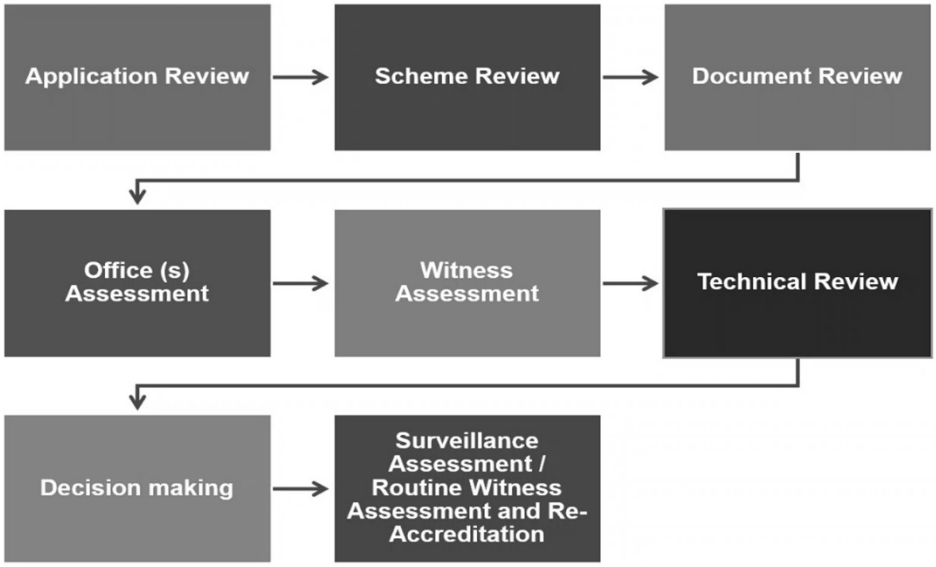
Equivalence Framework



Benefits Of Accreditation

- Assurance of Technical Competence, Reliability and Integrity of Conformity Assessment Bodies
- Customer Satisfaction, Minimizes Complaints
- Increased Operational Efficiency, Effective Risk Management, Saves Time & Money
- Facilitates Selection of Suppliers, Promotes Confidence in Imports, Avoids Re-testing/inspection
- Demonstrates Compliance to Standards / Regulations / Requirements
- Enhances Competitiveness, Marketing Advantage, Increased Business
- International Equivalence/Acceptance/Recognition through Multilateral Mutual Recognition Arrangements

Accreditation Process



INTERNATIONAL STANDARD

ISO/IEC 17065

First edition
2012-09-15

Conformity assessment — Requirements for bodies certifying products, processes and services

Aim of ISO/IEC 17065:2012

- The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfils specified requirements
- Parties that have an interest in certification include, but are not limited to:
  - a) the clients of the certification bodies;
  - b) the customers of the organizations whose products, processes or services are certified;
  - c) governmental authorities;
  - d) non-governmental organizations; and
  - e) consumers and other members of the public.

Introduction

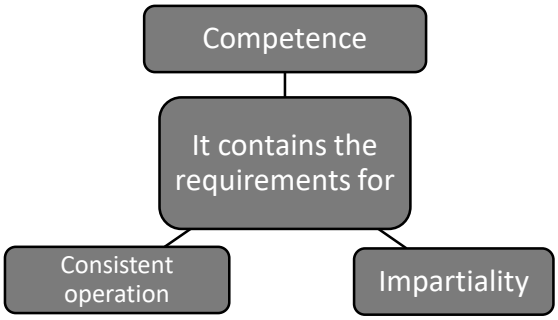
- Some product, process or service certification schemes may include initial testing or inspection and assessment of its suppliers' quality management systems,
- followed by surveillance that takes into account the quality management system and the testing or inspection of samples from the production and the open market

ISO/IEC 17065 Sections

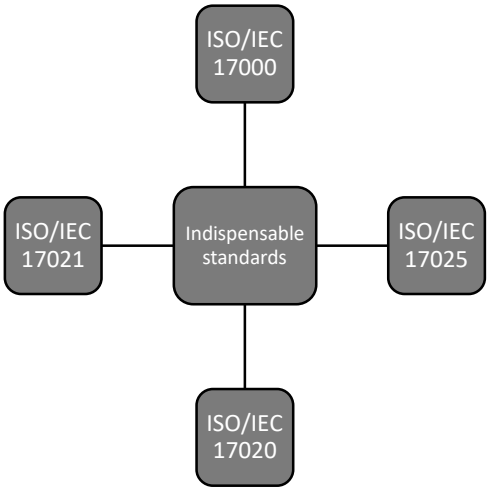
1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
5. Structural requirements
6. Resource requirements
7. Process requirements
8. Management system requirements

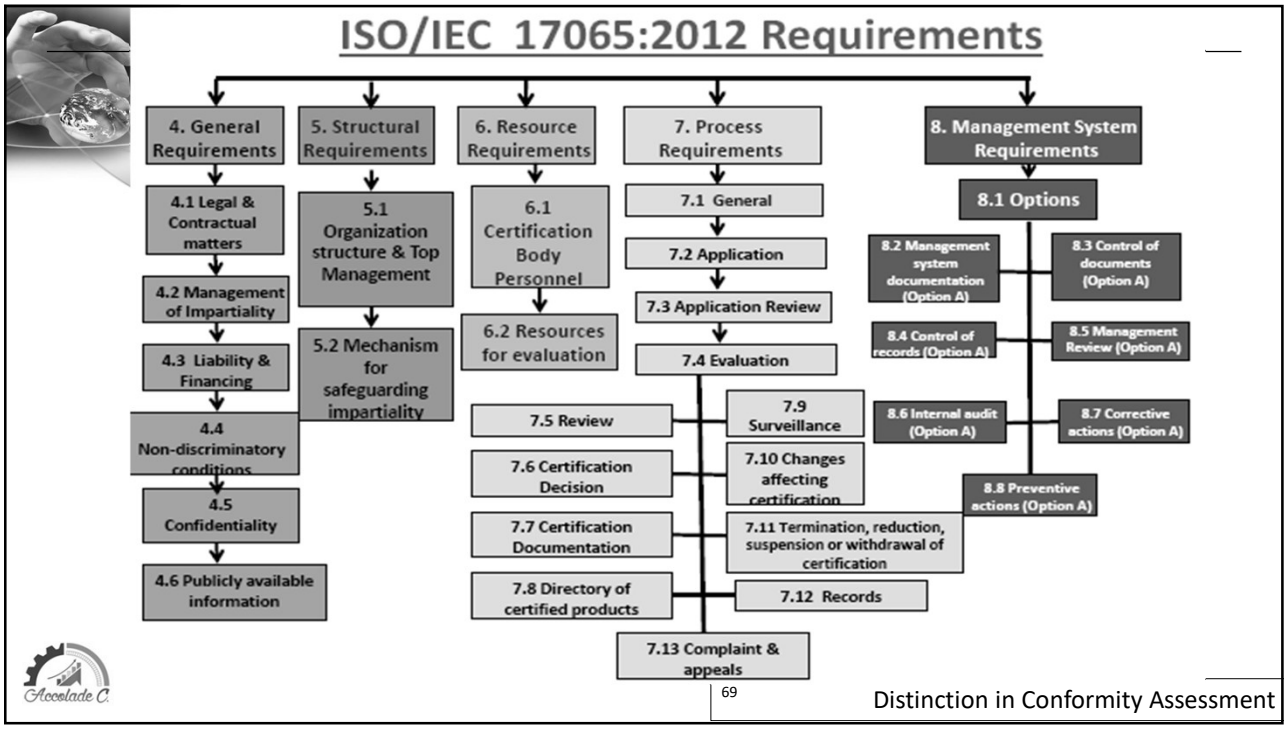
1 Scope

- product, process and service certification bodies
- certification of products, processes and services is a third-party conformity assessment activity
- the term “product” can be read as “process” or “service”, except in those instances where separate provisions are stated for “processes” or “services”



2 Normative references





General Requirements

- 4.1 Legal and contractual matters
- 4.2 Management of impartiality
- 4.3 Liability and financing
- 4.4 Non-discriminatory conditions
- 4.5 Confidentiality
- 4.6 Publicly available information

Distinction in Conformity Assessment

4.1 Legal and contractual matters

- CB must be a legal entity
- Certification Agreement –
  - Client must agree to 11 specific items
  - Referenced or included in agreement?
  - Signed by one or both parties?
- Use of license, certificates & marks of conformity
  - Exercises control as specified by the scheme

4.3 Liability and financing

- Adequate resources to cover liabilities
  - Insurance
  - Reserves
- Funding
  - Sustainable Operations
  - Source

4.4 Non-discriminatory conditions

- CB policy & procedures shall not be used to impede or inhibit access by applicants
- CB makes services accessible to all applicants
- Access not conditional upon size of the client, membership or prior work submitted
- Business decision exceptions allowed

4.5 Confidentiality

- Contractual agreements
  - Clients
  - Personnel – Internal & External
  - Subcontractors
  - Committee Members
- Subpoena Obligations

4.6 Publicly available information

- Information about the certification scheme
- Disclosure of how the CB obtains financial support and fees charged
- Rights and Duties of applicants & clients
- Information on procedures for handling complaints & appeals.

Structural Requirements
Impartiality Requirements

5.1 Organizational structure and top management

5.2 Mechanism for safeguarding impartiality

4.2 Management of impartiality

5.1 Organizational structure and top management

- Document organizational structure of personnel & Committees. Show duties, responsibility and line of authority.
- Formal rules for the appointment of Committees
- Agreements between legal entities for services

5.2 Mechanism for safeguarding impartiality

- Provides oversight on the management of impartiality
- Balanced interest representation
- Full access to information
- Ability to take independent action if proposals are ignored.

Assessment Criteria

- Is there objective evidence that:
  - A process is followed
  - CB determines acceptable risk level
  - The conclusions are reasonable

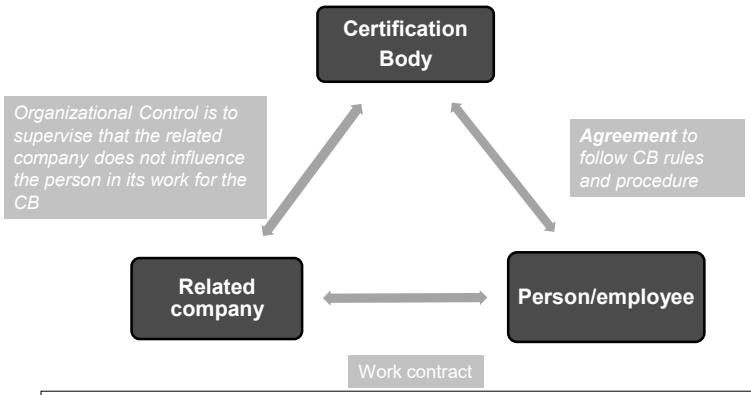
4.2 Management of impartiality

- No commercial, financial or other pressures to compromise impartiality (also 4.2.10)
- CB shall identify risks to impartiality on an ongoing basis.
- CB shall demonstrate how it eliminates/reduces risk
- Interrelationship with related legal entities
- Marketing & Sales (4.2.9)
- Applies to internal/external personnel & committees (4.2.12)

CB - Ownership - Management

- 4.2.6 – Legal Entity or any part of the same entity shall not…. See list in standard
- 4.2.7 – CB and activities of separate legal entity
- 4.2.8 – Management, Review, Certification Decision
  - CB and other legal entity – not the same management if consultancy in other legal entity
- Organizational or business risks to impartiality often overlooked
  - Personnel impartiality usually very complete

Possible Arrangement for Organizational Control



This relates to Clause 7.6.4 of ISO/IEC 17065.
This is one possibility for organizational control among many

Resource Requirements

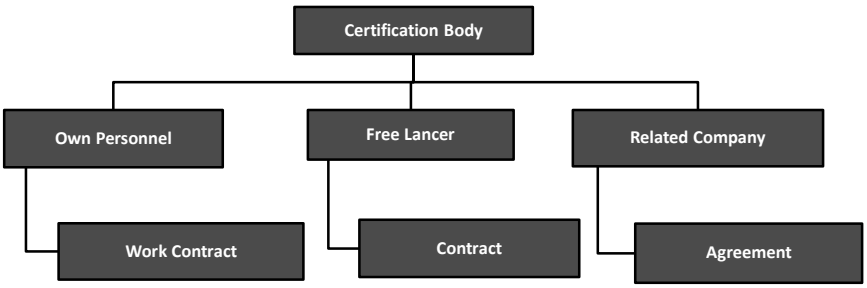
6.1 Certification body personnel

6.2 Resources for evaluation

Management of Competency

- The CB must apply procedures (6.1.2.1)
  - Determine competency criteria of each certification function
  - Identify the training requirements for each functional criteria
  - Have a means to determine demonstrated competency for the certification function
  - Have a process to appoint individuals for specific certification functions
  - Monitor the individual's functional performance

Examples of Resources Personnel



All those examples are covered in Clause 6 of ISO/IEC 17065

Competency

- The Certification Body personnel shall be competent for the functions they perform – 6.1.1.2
  - Technical judgments
  - Defining policies and implementing them
- Includes:
  - CB employees and related body employees
  - Contract workers
  - Subcontractors

Management of Functional Competency

- Determine Criteria for Functional Competence
- Education & Training needs to meet criteria
- Objective Evidence that personnel meet the criteria
- Authorize personnel for functions in the Certification Process and show Competency Matrix
- Monitor Functional Competence

Functional Competency

Which of these activities are part of **the** certification process?

- Quoting, Sales, Marketing
- Agreement
- Application assistance by CB personnel
- Application review
- Selection of evaluation activities (plan)
- Evaluation Activities (testing, inspection, management system auditing, other items needed for determination of conformance)
- Report on evaluation
- Corrective action review
- All evaluation activities completed report/records
- Review
- Decision
- Issuance of Certification Documentation
- Surveillance
- Termination/Withdrawal
- Suspension
- Extending/Reducing Scope
- Complaints/Appeals

Records

- Personnel in process (6.1.2.2)
  - Employer (often overlooked)
  - Competence assessment
  - Authorizations (new item for most)
- Contract with personnel in process (6.1.3)
  - Internal resource
  - External resource (discussion)

Process Requirements

- **7.1 General**
- **7.2 Application**
- **7.3 Application review**
- **7.4 Evaluation**
- **7.5 Review**
- **7.6 Certification decision**
- **7.7 Certification documentation**
- **7.8 Directory of certified products**
- **7.9 Surveillance**
- **7.10 Changes affecting certification**
- **7.11 Termination, reduction, suspension or withdrawal of certification**
- **7.12 Records**
- **7.13 Complaints and appeals**

Process Requirements

- Application – provides the necessary info to complete the certification process
- Application Review – Justification to Certify
  - Identify differences in understanding
  - Confirm Scope of Certification
  - Agreement on Standards & normative documents
  - Adequate means to evaluate the product
  - CB has competence & capability to Certify
  - New & innovative products – justification 7.3.3
  - Modifications & Transfers – 7.3.5

Process Requirements

- EVALUATION
  - Evaluation Plan defines tasks
    - Sampling, testing, inspection, audit
    - Quality Management
    - Construction - Drawings
  - Assignment of Staff, Competency
  - Information available to perform tasks
  - Document Evaluation Results - Opinion

Process Requirements

- REVIEW
  - CB shall assign person
  - Review by person not involved with evaluation process
  - Recommendation for certification documented
  - Reviewer can make the decision on certification

Process Requirements

- Decision on Certification
  - Certification Body responsible for its Decision on Certification
  - Can be committee not involved with the evaluation process
  - Performed by employee or contractor or an entity under the organizational control of the CB
  - CB's organization control: whole or majority ownership by the CB; majority participation on the Board of another entity; documented authority over another entity linked by ownership or board of director control

Process Requirements

- Certification Documentation
  - After certification agreement signed
  - Certification Requirements fulfilled
  - The decision to grant certification has been made
  - Expiration date
- Directory of Certified Products
  - CB or Scheme Owner
- Surveillance
  - Mark of Conformity
  - Product, Service or Process – Handling of Variations

Process Requirements

- Changes affecting Certification
  - Driven by the Scheme
    - CB responsible for communicating changes to its clients
    - CB shall verify implementation by client
  - Product changes
    - Contract Terms – Design Changes
    - Evaluation, Review, Decision, Certification Documents
  - Management changes
    - Key staff
    - Location

Process Requirements

- Termination
- Reduction
- Suspension
- Certification
- Records
  - Confidentiality
  - Retention

Process Requirements

- Complaints & Appeals
  - Documented Process
  - Record & Track
  - Information Gathering
  - Investigated by person outside the process
  - Decision & actions taken
  - Challenge

Confidentiality Clauses

- 4.5 Confidentiality
- 5.2.3 Safeguarding impartiality
- 6.1.1.3 Personnel keep information confidential
  - 6.1.3 Contract with personnel
- 6.2.2.3 Outsourcing
- 7.12 Records remain confidential
- 8.4.2 Records control
- Annex A (Informative)

Procedure Clauses

- 4.6 Information about procedures for certification
- 6.1.2 Management of competencies
- 6.2.2.4.c Qualifications and monitoring personnel
- 8.4 Records control
- 8.5 Management review
- 8.6 Internal audits
- 8.7 Corrective actions
- 8.8 Preventive action

Record Clauses

- 6.1.2.2 Personnel records
- 7.3.3 Justification for decision to undertake certification
- 7.10.3 Record of rationale for excluding any activity
- 7.12 Records required
- 7.13 Complaints and appeals
- 8.4 Control of records

Management System Requirements

- 8.1 Options
- 8.2 General management system documentation
- 8.3 Control of documents
- 8.4 Control of records
- 8.5 Management review
- 8.6 Internal audit
- 8.7 Corrective actions
- 8.8 Preventive actions

Section 8.1.3 - Options

- Management system requirements
  - internal process for self-assuring fulfillment of ISO/IEC 17065
- Option A
  - Sections 8.2 to 8.8
- Option B
  - an ISO 9001 QMS that takes account of the specific requirements in the sections 8.2 to 8.8 of ISO/IEC 17065 is an option
    - annex to ISO/PAS 17005:2008 shows how the ISO 9001 requirements would need to be read for meeting 8.1.3
    - 6 pages of commentary (based on ISO 9001:2000)
    - ISO 9001 current version is 2008

General Management System

- Documentation
  - Commitment to ISO/IEC 17065
  - Authority and responsibility for meeting ISO/IEC 17065
  - All information documented and linked to management system
  - Access to documents by all personnel

Requirements more prescriptive

- Document Control
- Record Control
- Management Review
- Internal Audit
- Corrective Action
- Preventive Action

Application of Related Standards

- ISO/IEC 17025
- ISO/IEC 17020
- ISO/IEC 17021

ISO/IEC 17025

- Testing part of evaluation
  - Remember: General requirements for the competence to carry out tests and calibrations using standard methods, non-standard methods and laboratory developed methods.
- The CB must review the test data in order to perform an evaluation of the information provided and ensure it is appropriate for the product evaluation.

ISO/IEC 17025

- Are the following applicable?
  - Equipment calibration at manufacture's site
  - Quality control testing during or end of production
  - Testing of product by manufacturer
  - “go” “no-go” testing (yes/no, on/off, presence/absense)

ISO/IEC 17020

- Inspection part of evaluation
  - What about auditing – Is it inspection?
  - What if scheme defines audit/inspection but not ISO/IEC 17020 based?
  - What if CB defines audit/inspection not using ISO/IEC 17020?
  - Inspection performed remotely
  - One time for life of certification

ISOIEC 17021

- Management system auditing part of evaluation
  - What if not ISO/IEC 9000 requirements
  - CB defines management system elements not based on ISO/IEC 9000
  - Scheme defines system elements not based on ISO/IEC 9000

Relevant requirements

- ISO/IEC 17065 indicates relevant requirements of related standards.
  - Who determines what is relevant?
  - Does the assessor write a nonconformance if he/she does not agree with what is relevant as determined by the scheme? by the CB?
  - Does the AB need a process to accept or not the decision of the CB or the scheme?

Application of Scheme ISO/IEC 17067

- Elements of Scheme
- Assessment to Scheme requirements
- AB review and acceptance of Scheme
- Scheme contradicts or excludes ISO/IEC 17065 requirements

Schemes - Assessment

- CB scheme
  - Must have document that defines scheme requirements to address ISO/IEC 17065 requirement
- Non-CB schemes
  - Scheme does not address ISO/IEC 17065 requirement
  - Scheme contradicts requirement
- The next several slides present where in the standard scheme requirements are found

Scheme Elements

- 4.1.2.2.f – Withdrawal, suspension, termination
- 4.1.2.2.g – Certification documents
- 4.1.2.2.h – Reference to product certification
- 4.1.2.2.i – Use of mark, product information
- 4.1.3.1 – Control over license, certificates, mark
- 4.1.3.2 – Incorrect use
- 4.2.6.e – Scheme may specify management system requirement
- 4.2.10 Note 1 Period specified for consultancy
- 4.6.a - Public information on certification

Scheme Elements

- 5.2.1.c Note 2 and 3 – Impartiality
- 5.2.4 Note 2 - limited interests
- 6.1.1.1 - Personnel
- 6.1.1.3 – Confidential information
- 6.1.2.1.a – Personnel competence criteria
- 6.1.2.1.b – Personnel training
- 6.2.1 - Internal Resources
- 6.2.2.1- External Resources
- 6.2.2.4 Note – qualifications of outsourced bodies

Scheme Elements

- 7.1.1 – Operate scheme
- 7.2 – Application
- 7.3.2 – Identify scheme
- 7.4.1 Note – Plan, general or specific
- 7.4.4 – Evaluation activities
- 7.4.5 – Evaluation results before application
- 7.4.9 Note 1 and 2 – Evaluation results
- 7.7.f – Information
- 7.8 – Directory
- 7.9.1 – Surveillance

Scheme Elements

- 7.10.1 – Changes affecting certification
- 7.10.3 – Documentation of revised surveillance activities
- 7.11.3 - Termination
- 7.11.4 - Suspension
- 7.11.5 – Suspension
- 7.12 – Records
- 7.12.3 – Re-evaluation
- 8.2.1 – Management system
- 8.5.2 Note – Scheme owners as interested party

Schemes

- What actions must the AB consider when:
  - Scheme contradicts ISO/IEC 17065
  - Scheme indicates certain clauses are not applicable
  - Not all requirements are implemented to meet ISO/IEC 17065
  - Scheme does not update or reference ISO/IEC 17065

Transition

- Accreditation Body Transition Policy
  - Communicated to certification bodies
  - Communicated to schemes
- When schemes do not make transition
  - When and what is communicated
  - The next slides present some possibilities

Gap Analysis or Full Assessment

- Full ISO/IEC 17065 not performed if scheme owner has not updated to ISO/IEC 17065.
  - For example, SQF,BRC, AECO, TCB, Energy Star, WaterSense, WaterMark, SFI/PEFC, etc.
  - The Scheme owner needs to decide what to do
  - Guidance or criteria from scheme owner related to ISO/IEC Guide 65 is used during the assessment so scheme requirements for ISO/IEC 17065 are not available

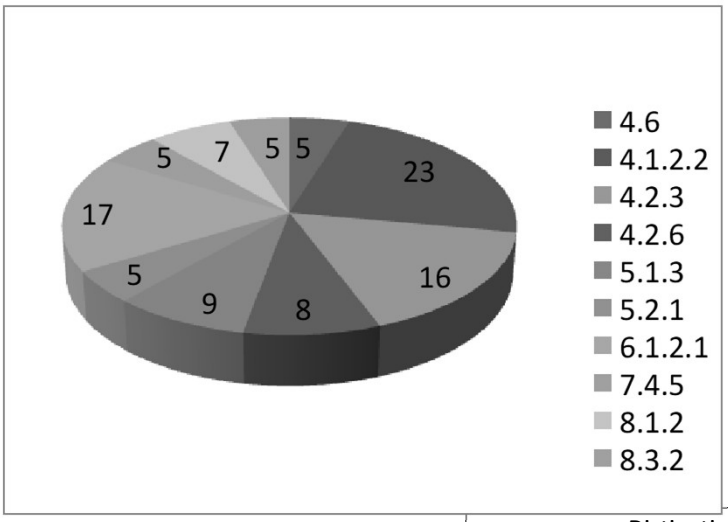
Gap Analysis or Full Assessment

- If the scheme belongs to the CB or scheme is updated to ISO/IEC 17065 – Then full assessment
- The CB must complete necessary changes and implement ISO/IEC 17065 - Then full assessment
  - CB shall change all the documents,
  - CB contact clients about the changes and request their comments,
  - CB must implement the new requirements or changes as appropriate
- Otherwise – Gap Analysis ???

Assessing a CB to ISO/IEC 17065

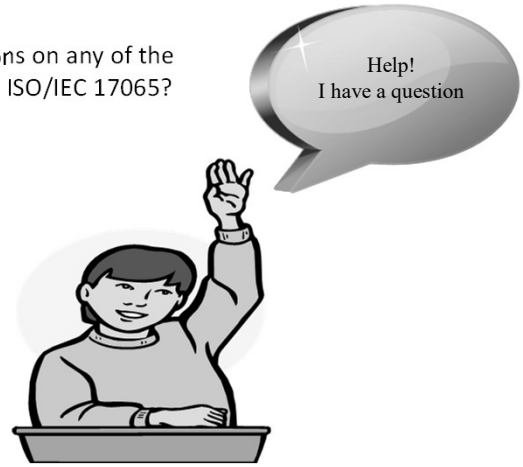
- Outcome depends on CB experience
  - Accredited to ISO/IEC 17021 – have impartiality mechanism
  - One legal entity with no relationships except testing and inspection bodies
  - Multinational CBs with over 100 legal entities – many for tax purposes but must be identified

Common Non-conformances ANSI 2013



Questions

- Any questions on any of the elements in ISO/IEC 17065?



Thank You

Introducing ISO/IEC 17067:2013

Conformity assessment –
fundamentals of product certification and guidelines for product certification schemes

ISO/IEC 17067:2013 - History

1980 *Certification – principles and practice* - ISO/ITC

1982 ISO/IEC Guide 28 *General rules for a model third-party certification system for products*

1983 ISO/IEC Guide 40 *General requirements for the acceptance of certification bodies*

1992 *Certification and related activities* - ISO/IEC

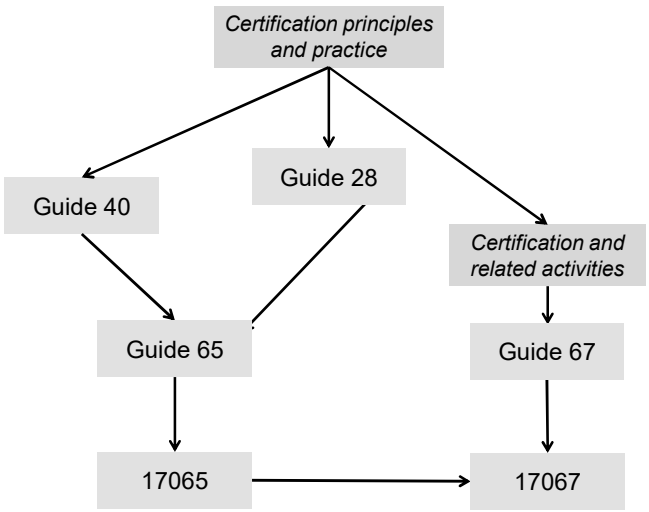
1996 ISO/IEC Guide 65 *General requirements for bodies operating product certification systems*

2004 ISO/IEC Guide 67 *Conformity assessment - Fundamentals of product certification*

2012 ISO/IEC 17065 *Conformity assessment - Requirements for bodies certifying products, processes and services*

2013 ISO/IEC 17067 *Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes*

ISO/IEC 17067:2013 – History (cont.)



Distinction in Conformity Assessment

Motivation for revising ISO/IEC Guide 67

In drafting ISO/IEC 17065, it was realised that a major impact on what a certification body does arises from the requirements of the product certification scheme(s) they are operating

Rather than trying to elaborate on these, it was decided simply to make reference to "the requirements of the scheme"

There are 31 such references in ISO/IEC 17065

ISO/IEC Guide 67 provided some basic information about product certification systems and it was decided that the Guide could be revised to include more information on product certification schemes

ISO/IEC Guide 67 to ISO/IEC 17067 – principle changes

- Title – extended to include product certification schemes
- Introduction – extended to include some of Guide 67, Clause 4
- Change from "system" to "scheme" as the focus
- Clarification of type and batch certification
- New section on product certification schemes providing information relating to "scheme" references in ISO/IEC 17065

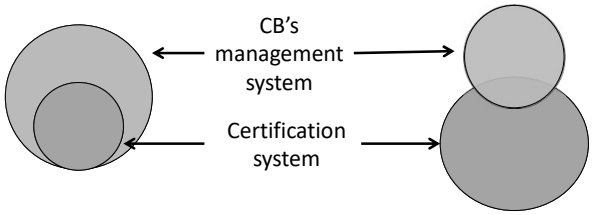
System ➔ Scheme

Confusion between certification system and managemen t system

- **For certification body's own scheme, certification system is part of management system**
- **For other schemes in which CB participates, certification system is external to CB's system**

Own scheme **Other scheme**

Certification <u>scheme</u> is the basic building block



Distinction in Conformity Assessment

Type and batch certification

"Certification and related activities" was clear on the distinction

- System 1 = type test
- System 7 = batch test
- System 8 = 100% test

Guide 67 merged Systems 7 & 8 into System 1 which was split into System 1a and System 1b

- Wording of 6.3.2 and 6.3.3 was not explicit

Now clarified that:

- Scheme type 1a = type test (5.3.2)
- Scheme type 1b = batch test (including 100%) (5.3.3)

Distinction in Conformity Assessment

ISO/IEC 17067 – what type of standard?

Shall = normative?

Should = informative?

ISO/IEC 17067 – what type of standard?

Should = informative

ISO/IEC 17067 – what type of standard?

Should = informative

Provides **guidelines** for those involved in developing and operating product certification schemes - particularly scheme owners

ISO/IEC17067: contents

- **Introduction**
- **1. Scope**
- **2. Normative references**
- **3. Definitions**
- **4. Product certification**
- **5. Product certification schemes**
- **6. Development and operation of a product certification scheme**

1. Scope

This International Standard describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.

It is intended for use by all with an interest in product certification, and especially by certification scheme owners.

2. Normative references

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

3. Definitions

3.1 certification system	• rules, procedures and management for carrying out certification
3.2 certification scheme	• **certification system** (3.1) related to specified products, to which the same specified requirements, specific rules and procedures apply
3.3 scheme owner	• person or organization responsible for developing and maintaining a specific **certification scheme** (3.2)

4. Product certification

4.1 Concept of product certification

- assessment and impartial, third party attestation that fulfilment of specified requirements has been demonstrated
- provides confidence to consumers, regulators, industry and other interested parties that products conform to specified requirements
- facilitates trade, market access, fair competition and consumer acceptance of products on a national, regional and international level

4. Product certification (cont.)

4.2 Objectives of product certification

- to address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of specified requirements
- to allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body
- provide confidence for those with an interest in fulfilment of requirements, and sufficient value so that suppliers can effectively market products

5. Product certification schemes

5.1 Basics – the functional approach

- Selection
- Determination
- Review
- Decision
- Attestation
- Surveillance (where required)

5. Product certification schemes

5.2 Functions and activities

- Each function is performed by carrying out certain conformity assessment activities, e.g. testing
- The activities will depend on the nature of the product and the production process
- Different types of scheme depending on type of surveillance
- Table 1: matrix of functions and activities for different types of scheme

Table 1
Building a product certification scheme

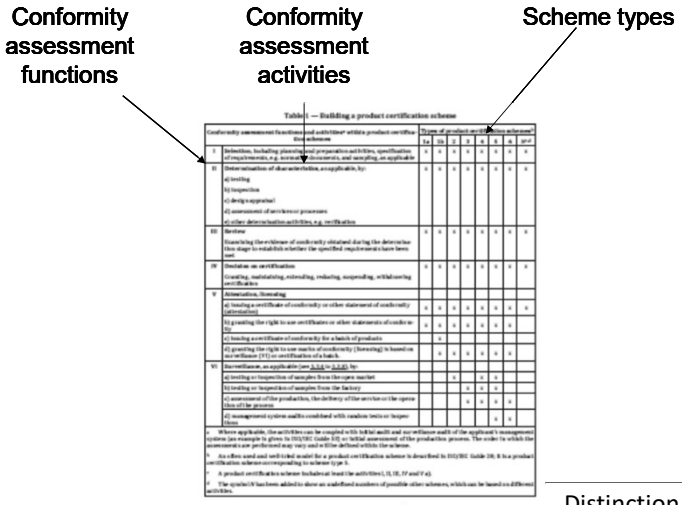


Table 1

Conformity assessment functions and activities[a] within product certification schemes		Types of product certification schemes[b]							
		1a	1b	2	3	4	5	6	Nc,d
I	Selection, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II	Determination of characteristics, as applicable, by:								
	a) testing	x	x	x	x	x	x	x	x
	b) inspection								
	c) design appraisal								
	d) assessment of services or processes								
	e) other determination activities, e.g. verification								
III	Review								
	Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met								
IV	Decision on certification								
	Granting, maintaining, extending, reducing, suspending, withdrawing certification								
V	Attestation, licensing								
	a) issuing a certificate of conformity or other statement of conformity (attestation)								
	b) granting the right to use certificates or other statements of conformity								
	c) issuing a certificate of conformity for a batch of products								
	d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.								

5. Product certification schemes

5.3 Types of product certification schemes

- Brief descriptions of the features of each scheme type.
- Not a definitive list – it is for the Scheme Owner in consultation with interested parties to define the activities
- All scheme types involve testing (or similar) to determine that a sample fulfills specified requirements
- In most cases the different scheme types involve different surveillance activities

5.3 Types of scheme

Scheme type 1a: type test. Attestation of conformity applies only to samples tested.

Scheme type 1b: batch test, including 100% testing. Attestation of conformity apples to all items in the batch

Scheme type 2: type test plus periodic testing of products from the market

Distinction in Conformity Assessment

5.3 Types of scheme (cont.)

Scheme type 3: type test plus periodic testing of products from the point of production plus periodic assessment of the production process

Scheme type 4: type test plus periodic testing of products from the point of production and/or the market plus periodic assessment of the production process

Scheme type 5: type test plus periodic assessment of production process and/or audit of management system plus periodic testing of products from point of production and/or the market

NB: Scheme types 3, 4 and 5 require initial assessment of production process and/or management system

Distinction in Conformity Assessment

5.3 Types of scheme (cont.)

Scheme type 6: applicable to certification of services and processes. Initial and periodic assessment of service or process plus initial assessment and periodic auditing of management system

NB: Insufficient attention yet at ISO level to service and process certification

Scheme type n: included in Table 1 but no separate clause in 5.3 Indicates that scheme owner can select activities that suit the purpose of the scheme, in consultation with stakeholders

6. Development and operation of a product certification scheme

In response to many references in ISO/IEC 17065*, new clause to provide guidelines for scheme owners and others

* ISO/IEC 17065:2012, *Conformity assessment – Requirements for bodies certifying products, processes and services*

6. Development and operation of a product certification scheme

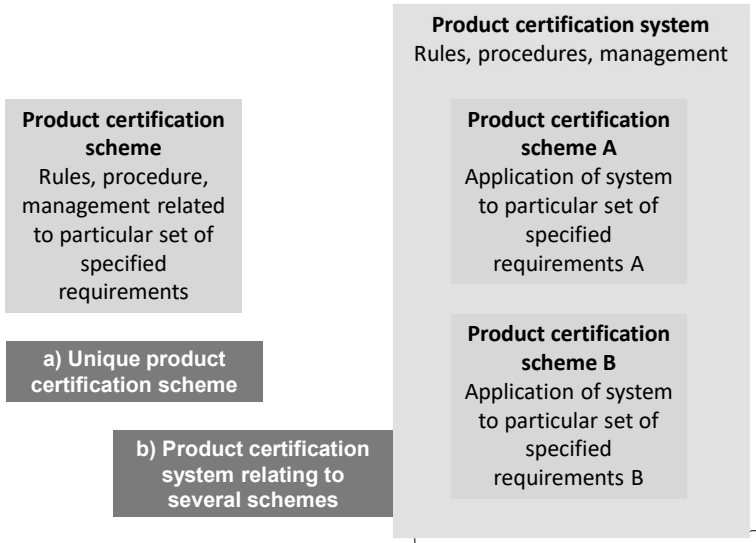
- 6.1 General
- 6.2 Relationship between product certification scheme and product certification system
- 6.3 Scheme owner
- 6.4 Development of product certification schemes
- 6.5 Content of a scheme
- 6.6 Maintenance and improvement of a scheme
- 6.7 Scheme documentation

17067: 6.1 General

This clause provides guidelines on how to develop and operate a product certification scheme.

It is particularly relevant to those persons and organizations that are considering the establishment of a scheme or acting as a stakeholder (e.g. manufacturer, service provider, certification body, customer or public authority).

6.2 Relationship between scheme and system



6.3 Scheme owner

6.3.1 Types of scheme owner –

- Certification body,
- Other – regulatory body, trade association, group of certification bodies, etc.

6.3.2 Combine several schemes within product certification system

6.3.3 Legal entity

6.3.4 Full responsibility for objectives, content, integrity of scheme

6.3.5 Maintain scheme and provide guidance

6.3 Scheme owner (cont)

- 6.3.6 Set up structure for operation and management of scheme
- 6.3.7 Document content of scheme
- 6.3.8 Scheme developed by competent persons
- 6.3.9 Arrangements to protect confidentiality of information
- 6.3.10 Evaluate and manage risks/liabilities arising from scheme
- 6.3.11 Arrangements to cover liabilities arising from owner's activities
- 6.3.12 Financial stability and resources

6.4 Development of product certification schemes

- 6.4.1 Purpose of scheme
- 6.4.2 Understand assumptions, influences and consequences
- 6.4.3 Identify stakeholders and seek input
- 6.4.4 Agree fundamental scheme principles with stakeholders
- 6.4.5 Information on scheme publicly available – transparency, understanding, acceptance

6.5 Content of a scheme

6.5.1 General - elements of a scheme

- Scope
- Product requirements
- CA activities
- Certification requirements
- Requirements for CA bodies : accreditation? peer assessment?
- CA methods and procedures
- Information supplied by client

6.5 Content of a scheme (cont.)

6.5.1 General - elements of a scheme (cont.)

- Statement of conformity
- Mark of conformity
- Use of certificate and mark
- Resources for operating scheme - impartiality, competence, outsourcing
- Reporting results of determination and surveillance activities
- Dealing with non-conformities: client, product
- Surveillance procedures

6.5 Content of a scheme (cont.)

6.5.1 General - elements of a scheme (cont.)

- Criteria for access to scheme: CBs, clients
- Directory of certified products
- Contracts: owner, CB, client
- Conditions for certification: granting, withdrawing, etc.
- Clients' complaints records, need for verification by CBs
- Clients' reference to scheme in publicity material
- Records to be retained by scheme owner and CBs

6.5 Content of a scheme (cont.)

- 6.5.1 General – elements of a scheme
- 6.5.2 Sampling
- 6.5.3 Acceptance of conformity assessment results
- 6.5.4 Outsourcing of conformity assessment activities
- 6.5.5 Complaints and appeals to scheme owner
- 6.5.6 Licensing and control of mark

6.5 Content of a scheme (cont)

- 6.5.7 Surveillance
- 6.5.8 Non-conforming product
- 6.5.9 Reporting to scheme owner
- 6.5.10 Subcontracting of operation of scheme
- 6.5.11 Marketing
- 6.5.12 Fraudulent claim of certification

6.6 Maintenance and improvement of a scheme

- 6.6.1 Review of scheme operation
- 6.6.2 Changes in specified requirements
- 6.6.3 Other changes to the scheme

6.7 Scheme documentation

Scheme owner:

- Creates, controls and maintains adequate documentation for operation, maintenance and improvement of scheme

Documentation specifies:

- rules
- operating procedures
- responsibilities for governance of the scheme

ISO/IEC 17067 - Summary

- Revises and updates ISO/IEC Guide 67
- Changes focus from system to scheme
- Provides information on scheme requirements as referenced in ISO/IEC 17065
- Emphasises crucial role of Scheme Owner
- Clarifies difference between type and batch certification schemes

Ongoing issues

- Updating of ISO/IEC Guides 28 and 53 ➔ ISO/IEC TR 17026
- Further consideration of help with certification of services and processes

For more information, please visit
www.accolade-cert.com

Mobile# +8801711420512 (WhatsApp)
Email: accolade.cert@gmail.com

1

Internal Auditor Training course on ISO 22000:2018 Food Safety Management System

25-26 June 2025

Dhaka, Bangladesh

Trainer:

Dr. Kulsum Begum Chowdhury

Delegate Introduction

► Interview in pairs (6 minutes per interview / presentation up to 2 minutes)

Information to be obtained

- Full name
- Position, name of Dept./Division/organization for which they work, and role within that organisation
- Career background
- Their knowledge of ISO 22000:2018 ranked from 1 to 10
- Auditing experience - first, second or third party
- Personal objective for attending the course
- Any valuable information allowing successful communication

Records will be used for team allocation

Dr. Kulsum Begum Chowdhury







ABOUT THE COURSE

Course Title	Internal Auditor Training course on ISO 22000:2018
Level	Professional
Course short Description:	The aim of this course is to provide delegates with the knowledge and skills required to perform first party audit on Food Safety management systems against ISO 22000 standard in accordance with ISO 19011.
Assessment:	Continuous assessment and 0.5 hours examination.
Recommended prior knowledge:	The Plan, Do, Check, Act (PDCA) cycle, Core elements of a management system and the interrelationship. Fundamental concepts of Food Safety management and the requirements of ISO 22000:2018 Standard and terms and definitions.

ABOUT THE COURSE

➢ **Learning Objectives (Knowledge):**

- Describe the fundamental **purpose** of a **F**ood **S**afety **M**anagement **S**ystem and explain the principles, processes and techniques used for the **assessment** and **management** of food safety hazards, including the significance of these for FSMS auditors.

- Explain the purpose, content and interrelationship of the following: management system standards; ISO 22000:2018, the ISO 9000:2000 series; guidance documents (ISO 22004:2005, ISO 15161:2002); industry practice; standard operating procedures; and the legislative framework relevant to a FSMS.

ABOUT THE COURSE

➢ **Learning Objectives (Skills):**

- Interpret the requirements of ISO 22000:2005 and ISO 22000-1 in the context of an audit an organization's FSMS with particular reference to:
  - The effectiveness of the organization's management of risk through its food safety risk assessment and control planning.
  - The capability of an organization to maintain and exceed compliance with legislative requirements.
  - The adequacy of the organization's emergency preparedness and response.
  - The implementation of operational risk control, monitoring and measurement.
  - The continuous improvement of food safety management system performance.
- Plan, conduct, report and follow up a food safety management system audit in accordance with ISO 19011.

House rules

- Facilities

Courtesy: mobile phones to be muted/ switched off

Emergency situations

Confidentiality

Course Timing

Day 1: **09:00 to 17:00**

Day 2: **09:00 to 17:00**

Morning tea/coffee break: 10:30

Lunch & prayer break: 13:00 to 14:00

Afternoon tea/coffee break: 16:00

8

Course Structure

9

Learning Methods

- Tutorials
- Discussions
- Exercises
- Tutor- Delegate interaction
- Share of experience

Evaluation Methods

- Continuous Assessment
- Formal Examination
  - 30 min
  - Open book (Only the standard)

TYPE OF AUDITS

10

A. FIRST PARTY AUDIT

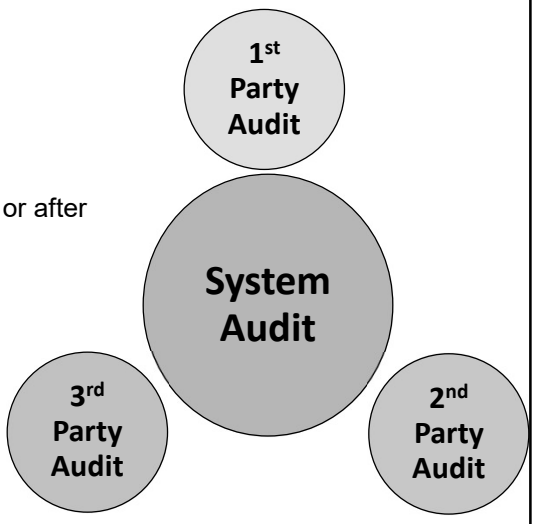
Audits carried out by a company on its own systems.

B. SECOND PARTY AUDIT

Audits carried out by one organization on another prior to or after contract placement.

C. THIRD PARTY AUDIT

Audits carried out by independent authorized organizations.



Delegate feedback – Course appraisal

- The course appraisal form is included in delegate manual.
- Your feedback is important information for further improvement of our training services.
- Summaries are prepared for each course and are an important input to the management review.
- Please fill it as the course progresses

12

Introduction to ISO

ISO 22000: Food Safety

What is ISO?

- **International Organization for Standardization**
  - Non-governmental
  - A bridge between public and private sectors

►**An ISO Standard**

- Voluntary (no legal authority)
- Purpose:
  - ➢ To facilitate exchanges
  - ➢ Meet a real need (market driven)
- Work of experts - achieved by consensus
- Auditable requirements

►**Well-known ISO management standards used by Organization:**

- ISO 9001 – Quality Management Systems (QMS)
- ISO 14001 – Environmental Management Systems (EMS)
- ISO 45001 – Occupational Health & Safety Management Systems (OHSMS)

About ISO

- **Non-governmental organization (NGO) established in 1947, based in Geneva, Switzerland**
- **Has a membership of over 169 national standards institutes from countries in all regions of the world**
- **The world's largest developer of voluntary International Standards, based on global and market relevance**

ISO International Organization for Standardization

15

25701

International Standards covering almost all aspects of technology, management and manufacturing.

172

Members representing ISO in their country. There is only one member per country.

843

Technical committees and subcommittees to take care of standards development.

ISO 22000: Food Safety

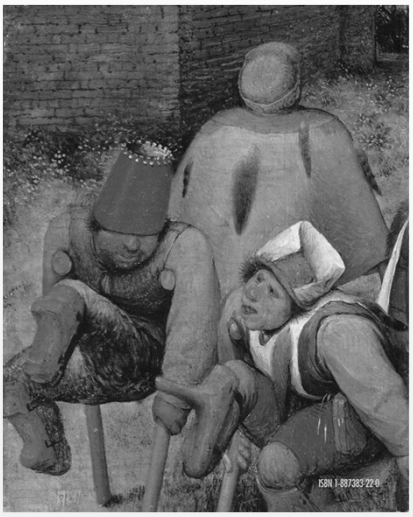
- ► Society / authority approach
  - Healthy work force
  - Health costs
  - Political acceptability
- ►Company approach
  - Company defence
  - Brand defense
  - Sector defense

The risk of getting ill

or

The fear of getting ill

Food safety relevance



Extract from "The Beggars" by Pieter Brügel the Older

Current and future deliverables of ISO related to FSMS

- FSSC 22000: This is a widely recognized Global Food Safety Initiative (GFSI) benchmarked certification scheme-
- It incorporates ISO 22000, relevant ISO/TS 22002 PRPs, and additional scheme-specific requirements
- (e.g., food fraud, food defense, quality control, allergen management, food safety and quality culture, food loss and waste)
- FSSC 22000 Version 6 became mandatory from April 1, 2024
- Organizations previously certified to Version 5.1 must complete their upgrade audit to Version 6 before March 31, 2025.
- Amendments to ISO 22000:2018:
- An amendment, ISO 22000:2018/Amd. 1:2024, has been introduced. This amendment adds requirements under Clauses 4.1 and 4.2, emphasizing the need for organizations in the food chain to assess and address the impacts of climate change on food safety and their FSMS.

Current and future deliverables of ISO related to FSMS

- **ISO 22000:2018: Food safety management system- Requirements with guidance for use**
- ISO/TS 22002 series: These are technical specifications that provide detailed Prerequisite Programs (PRPs) for specific sectors within the food chain. Examples include:
- ISO/TS 22002-1: For food manufacturing.
- ISO/TS 22002-2: For catering.
- ISO/TS 22002-3: For farming.
- ISO/TS 22002-4: For food packaging manufacturing.
- ISO/TS 22002-5: For transport and storage.
- ISO/TS 22002-6: For feed and animal food production.
- ISO 22003-1:2022: Requirements for bodies providing audit and certification of food safety management systems
- ISO22004:2014: Food safety management systems —Guidance on the application of ISO 22000
- ISO 22005:2007: Traceability in the feed and food chain

ISO 22000: Content

The Four Pillars of ISO 22000

- ► Management
  - Policy, commitment, organization, resources
- ►HACCP plan
  - Critical Control Points controlled in the classical way
- ►Prerequisite programmes
  - Everything else that needs to be controlled
- ►Communication
  - Active internal and external communication is required

ISO 22000: Food Safety

The risk based principles of HACCP

Only management system requirements are given beforehand

Control measures, monitoring, verification are planned according to the organization's needs

Hazards – listed and evaluated

- if needed they must be controlled

Control measures – listed and evaluated

- if needed they must be controlled

ISO 22000: Food Safety

The risk based principles of HACCP

The challenge for the company:

To minimize the control measures needed to monitor and verify

- still keeping the hazards under control

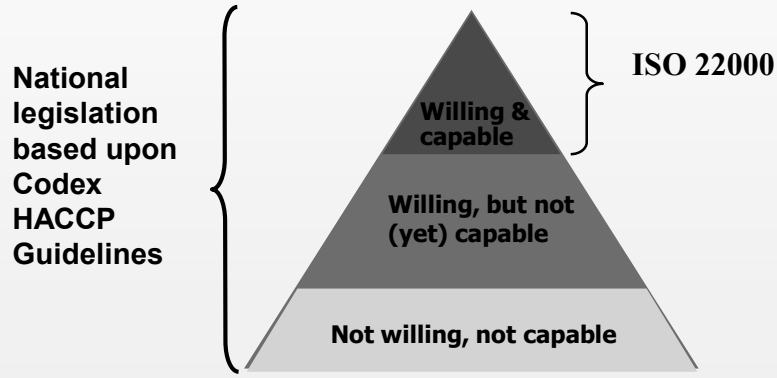
The challenge for the auditor:

To identify if all relevant hazards are identified, correctly evaluated and the control measures are likely to be efficient

ISO 22000: Food Safety

Target groups for ISO 22000

► Scope: All types of organizations within the food chain (advanced, less advanced, with no CCPs)



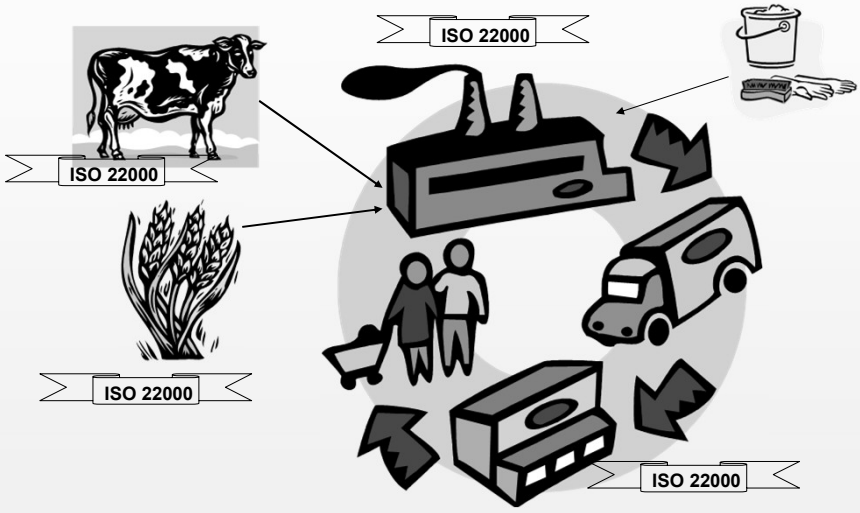
ISO 22000: Food Safety

Why does industry need ISO 22000?

- ISO 9001 does not specifically deal with food safety and does not address stringency (unspecific)
- Too many local standards (⇒ confusing)
- Need for a harmonized auditable approach (documentation ability)
- Desire for system improvements
  - Communication among trade partners
  - Resource optimization (internally & along food chains)
  - Better documentation
- Desire for improving food safety management
  - Better planning, less post-process verification
  - Management of the food chain continuum
  - More efficient and dynamic hazard control
  - Systematic management of prerequisite programs

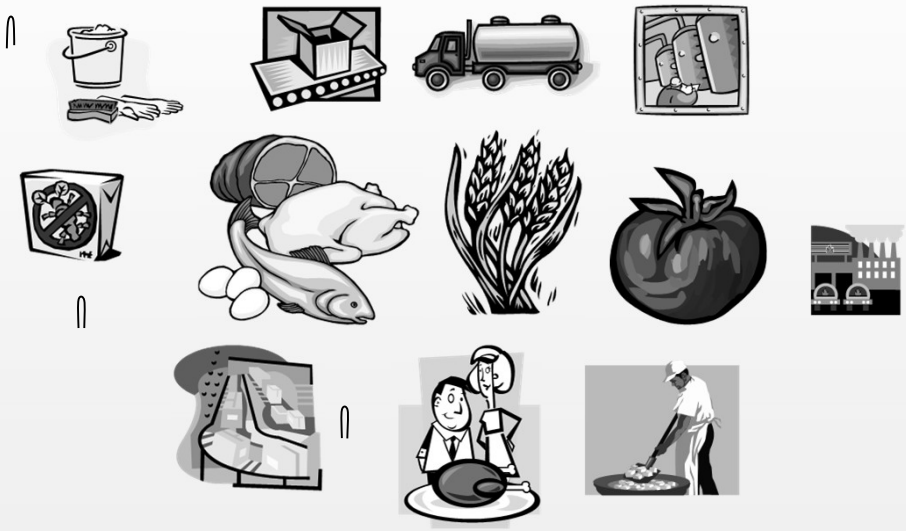
ISO 22000: Food Safety

The Food Chain



ISO 22000: Food Safety

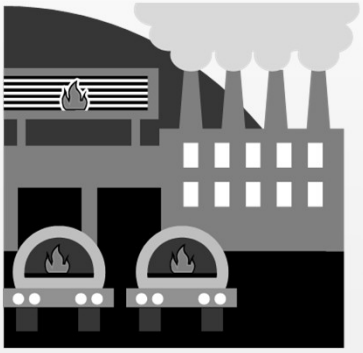
Interactive Communication



ISO 22000: Food Safety

Prerequisite Programs

- Infrastructure and maintenance
- Cleaning, pest control, personal hygiene etc.



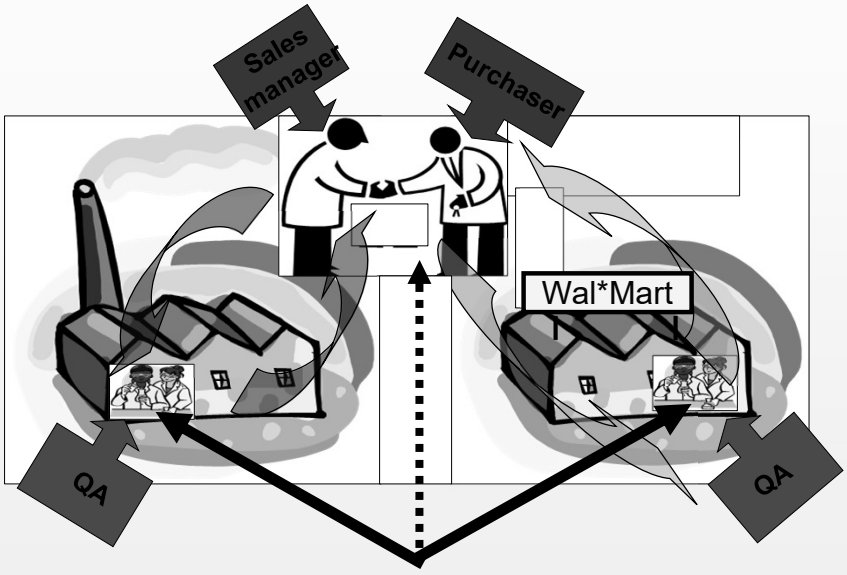
ISO 22000: Food Safety

Scope of ISO 22000

- ISO 22000 specifies requirements for a food safety management system where an organisation needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption.
- It is applicable to all organizations, regardless of size, which are involved in any aspect of the food chain and want to implement systems that consistently provide safe products. The means of meeting any requirements of this International Standard can be accomplished through the use of internal and/or external resources.

ISO 22000: Food Safety

Communication with Customers



TYPE OF AUDITS

A. FIRST PARTY AUDIT

Audits carried out by a company on its own systems.

B. SECOND PARTY AUDIT

Audits carried out by one organization on another prior to or after contract placement.

C. THIRD PARTY AUDIT
Audits carried out by independent accredited organizations.

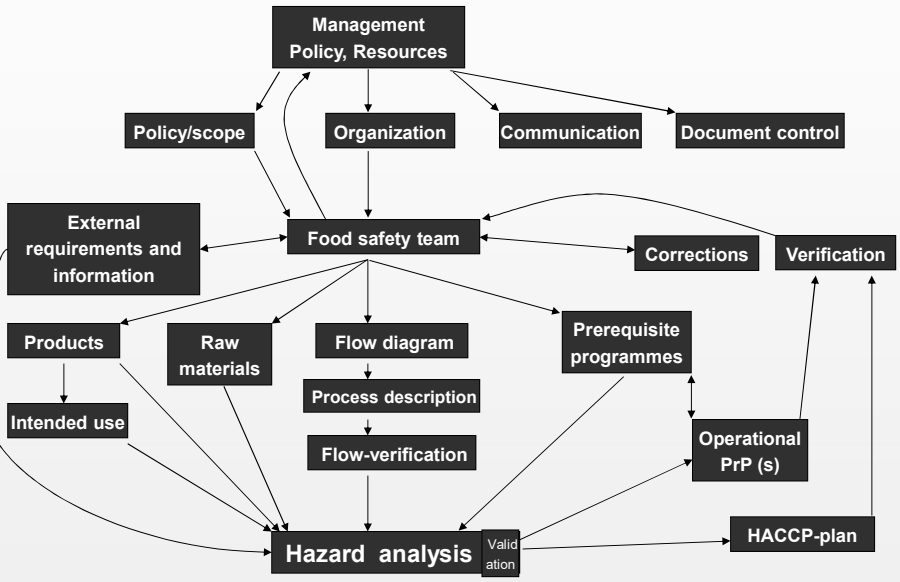
ISO 22000: Food Safety

Scope of ISO 22000

- ISO 22000 specifies requirements for an organization covering:
  - a food safety management system ensuring that the food are safe for the consumer,
  - customer requirements that relate to food safety,
  - communication with customers and others along the food chain,
  - compliance with statutory and regulatory food safety requirements,
  - conforms with stated food safety policy,
  - demonstrate conformity,
  - seek certification or registration.

ISO 22000: Food Safety

Overview of ISO 22000



ISO 22000: Food Safety

Terms and definitions

The terminology of ISO 9000 applies unless otherwise specified

The company can make its own translation of wording BUT there has to be a clear explanation and connection to the definitions in ISO 22000

HAZARD, PRP, O-PRP, CCP

LDC graduation: Key challenges and opportunities

33

- **Challenges:**
- **WTO's rules**
- **Loss of duty-free, quota-free access**
- **LDC specific ODA support**
- **UN subscription would increase**
- **Intellectual property rights: Pharmaceutical industries to be impacted most**

- **Opportunities:**
- **Improved image, better credit rating**
- **Graduation will improve influence in the regional and global level**

34

Genesis of FSMS

35

History of Food Safety Management System

I. Historical Evolution of Food Safety:

•**Ancient Times:** Early concerns focused on basic preservation techniques and visual inspection, though the understanding of microbial contamination was absent. Religious and cultural beliefs also influenced early food safety practices.

•**Middle Ages & Renaissance:** Regulations began to appear in the form of guild ordinances and municipal bylaws, aimed at maintaining basic hygiene in markets and taverns. Incremental progress in preservation continued.

History of Food Safety Management System

36

19th Century - Scientific Revolution:

Louis Pasteur's work on fermentation and microbial spoilage laid the foundation for modern microbiology and pasteurization, dramatically improving food safety.

Early 20th Century (e.g., in the US): Public outcry (e.g., from Upton Sinclair's "The Jungle") led to the establishment of regulatory bodies like the USDA and FDA and the passing of foundational laws like the Pure Food and Drug Act and the Meat Inspection Act. These marked the beginning of modern regulatory oversight.

History of Food Safety Management System

37

Early Developments and the Genesis of ISO 22000:

•**1960s:** The **Codex Alimentarius Commission (CAC)** developed the **Hazard Analysis and Critical Control Point (HACCP)** system. This was a significant preventive approach to food safety, identifying and controlling hazards that could lead to foodborne illness.

•**Early 1990s:** The food industry, particularly in the European Union, started adopting the **ISO 9000:1987 series of standards** for quality management. Simultaneously, the USDA recognized HACCP systems in the US.

•**Late 1990s - Early 2000s:** As the food industry became more globalized, a clear need emerged for a unified, international standard for food safety. Different countries had their own rules, and while HACCP was widely recognized, a single comprehensive guideline was missing. This led the International Organization for Standardization (ISO) to begin work on a new food safety standard.

•**2005: First Publication of ISO 22000.** ISO 22000 was first published in **2005**. It was a landmark achievement, becoming the first international standard for FSMS. It harmonized global food safety practices by integrating the principles of HACCP with prerequisite programs (PRPs) and incorporating elements from the ISO 9001 quality management standard. This initial version emphasized risk management, supply chain communication, and continuous improvement, though it was considered more procedural than principle-based.

History of Food Safety Management System

38

The Development and Key Changes Leading to ISO 22000:2018:

Over the years, the food industry landscape, food safety science, and consumer expectations continued to evolve, highlighting the need for a revision of ISO 22000. This led to a thorough revision process, culminating in the **publication of ISO 22000:2018 on June 18, 2018.**

The key changes in the 2018 revision include:

1.Adoption of the High-Level Structure (HLS) / Annex SL.
2.Enhanced Risk-Based Thinking:
- Operational risks: Related to the food safety hazards themselves (HACCP).
- Management system risks

3.Clarification of PDCA Cycles:
4.Strengthened Leadership and Management Commitment
5.More Prescriptive Communication Requirements
6.Less Strict Requirements for a Food Safety Manual
7.Expanded Scope
8.Revised Definitions
9.Control of Externally-Provided Processes, Products, or Services:
10.the focus on establishing and monitoring objectives for the FSMS

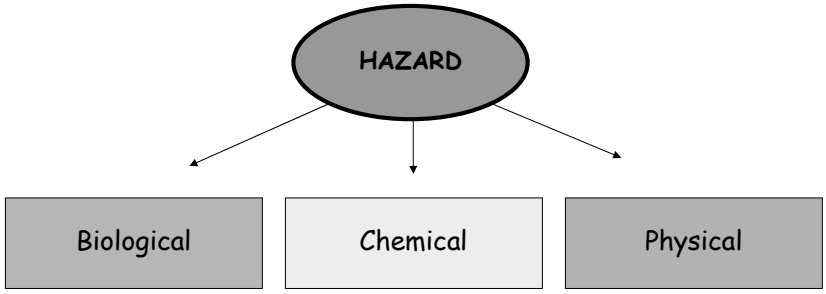
Basic Understanding of FSMS

What is Food Safety

You tell me… what does Food Safety mean to you?

What is Food Safety

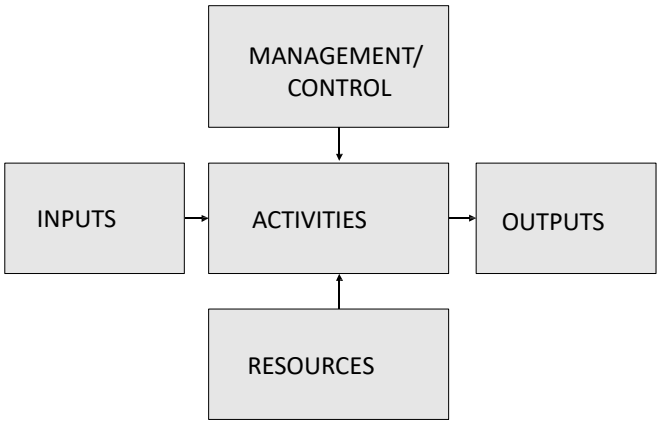
It is the condition which ensures that food will not cause harm to the consumer when prepared and/or eaten according to their intended use.



FOOD SAFETY MANAGEMENT SYSTEM PRINCIPLES

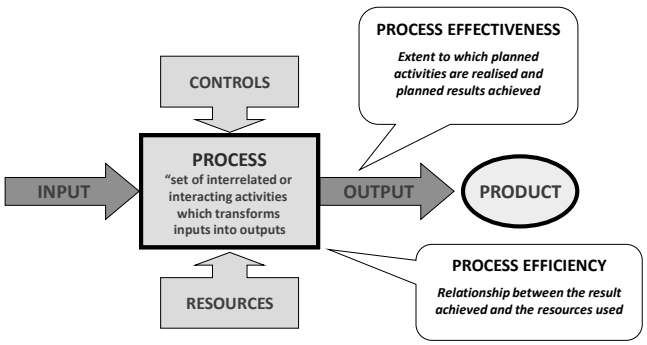
- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence based decision making
- Relationship Management

A PROCESS



29

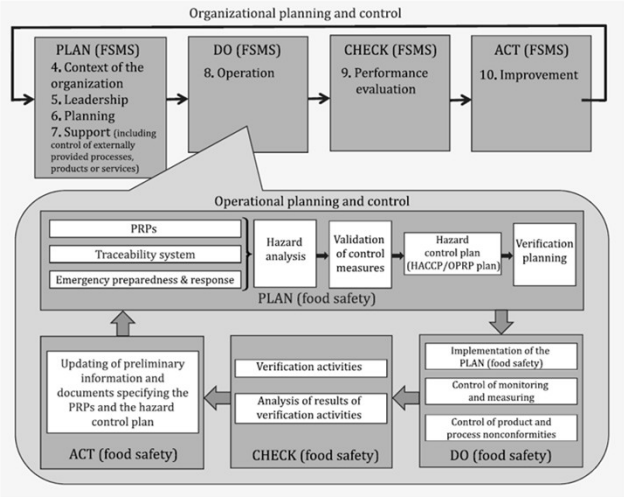
Process Approach



A desired result is achieved more efficiently when activities and related resources are managed as a process

22

FOOD SAFETY MANAGEMENT PROCESS MODEL



ISO 22000 STANDARD , ISO 9000 SERIES OF STANDARDS & AUDITING GUIDELINE

ISO 22000	FSMS - Requirements
ISO 9000	QMS - Fundamentals and Vocabulary
ISO 19011	Guidelines for auditing management systems

Exercise 1: Definition Matching

NEW AND REVISED
TERMS AND DEFINITIONS

COMPETENCE

Ability to apply knowledge and skills to achieve intended results

CONTINUAL IMPROVEMENT

Recurring activities to enhance performance

CONTAMINATION

introduction or occurrence of a contaminant including a food safety hazard in a product or processing environment

CONTROL MEASURE

action or activity that is essential to prevent a significant food safety hazard or reduce it to an acceptable level

CORRECTIVE ACTION

Action to eliminate the cause of a nonconformity and to prevent recurrence

DOCUMENTED INFORMATION

Information required to be controlled and maintained by an organization and the medium on which it is contained.

CRITICAL CONTROL POINT
CCP

step in the process at which control measure(s) is (are) applied to prevent or reduce a significant food safety hazard to an acceptable level, and defined critical limit(s) and measurement enable the application of corrections

CRITICAL LIMIT

measurable value which separates acceptability from unacceptability

FEED

single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to food-producing animals

FOOD

food is intended for consumption by humans and animals, and includes feed and animal food;

ANIMAL FOOD

animal food is intended to be fed to non-food-producing animals, such as pets.

FOOD CHAIN

sequence of the stages in the production, processing, distribution, storage and handling of a *food* and its ingredients, from primary production to consumption

INTERESTED PARTY

Person organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.

MANAGEMENT SYSTEM

Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve these objectives

FOOD SAFETY

assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use

MEASUREMENT

Process to determine a value.

MONITORING

Determining the status of a system, a process a product, a service or an activity.

FOOD SAFETY HAZARD

biological, chemical or physical agent in food with the potential to cause an adverse health effect

OPERATIONAL PREREQUISITE PROGRAMME
OPRP

control or combination of control measures applied to prevent or reduce a significant food safety hazard to an acceptable level, and where action criterion and measurement or observation enable effective control of the process and/or product

PREREQUISITE PROGRAMME
PRP

basic conditions and activities that are necessary within the organization and throughout the food chain to maintain food safety

TRACEABILITY

ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

ORGANIZATION

Person or a group of people that has its own functions with responsibilities authorities and relationships to achieve its objectives.

OUTSOURCE

Make a arrangement where an external organization performs part of the organizations function or process

PERFORMANCE

Measurable results

PROCESS

Set of interrelated or interacting activities that use inputs to deliver an intended results.

REQUIREMENT

Need or expectation that is stated, generally implied or obligatory at the highest level

RISK

Effect of uncertainty.

TOP MANAGEMENT

Person or group of people who directs and controls an organization

ISO 22000:2018 Standard Overview

0 Introduction
1 Scope
2 Normative references
3 Terms and definitions
4 Context of organization
5 Leadership
6 Planning
7 Support
8 Operation
9 Performance evaluation
10 Improvement

Clause 1 – 2 – 3

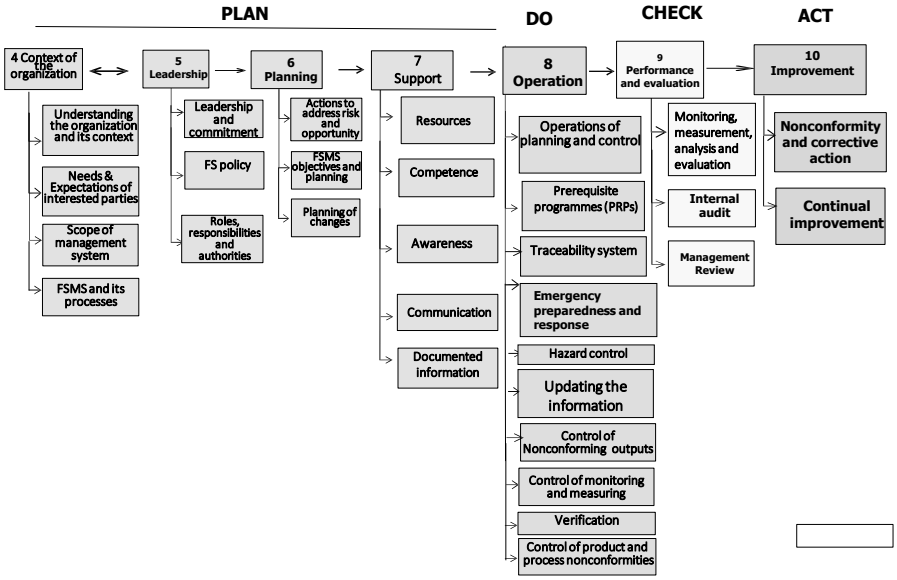
- **Clause 1 – This standard specifies requirements for a FSMS when an organization -**

This document specifies requirements for a food safety management system (FSMS) to enable an

organization that is directly or indirectly involved in the food chain.

- **Clause 2 – normative reference**
- **Clause 3 – terms and definitions**

ISO 22000:2018 FSMS Structure



4.0 Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the food safety management system

4.4 Food Safety Management System and its processes

4.1 Understanding the organization and its context

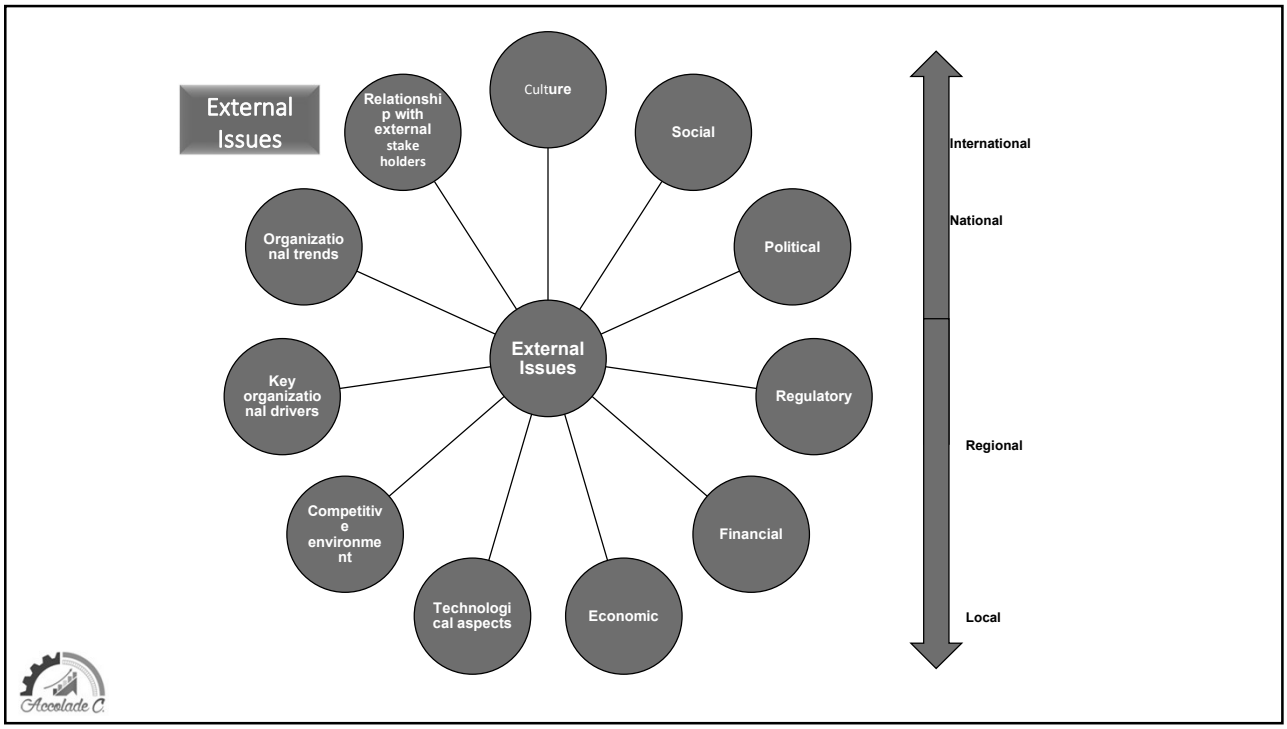
- **Determine external issues**
- **Determine internal issues**
- **All issues relevant to its purpose**
- **Issues relevant to strategic direction**
- **Consider issues that affect ability to achieve the intended result of FSMS.**

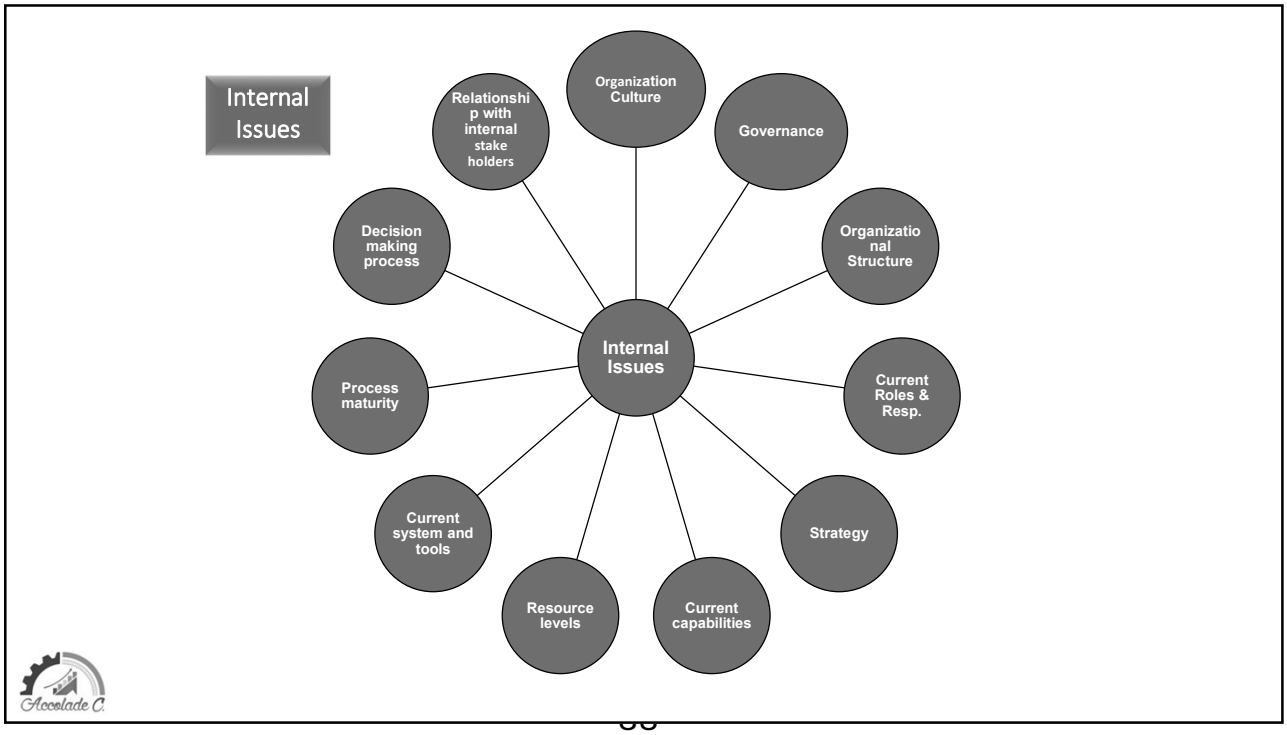
Considerations to determine issues

For determining relevant external and internal issues, consider those arising from:

- **Changes and trends having impact on the objectives of the organization**
- **Relationships with and perceptions and values of relevant interested parties**
- **Governance issues, strategic priorities, internal policies and commitments**
- **Resource availability and priorities and technological change**

Understanding the organization and its context is very important to make the good system and some formal system of collecting such information needs to be established


External Issues
Culture
Relationship with external stake holders
Social
Organizational trends
Political
External Issues
Key organizational drivers
Regulatory
Competitive environment
Financial
Technological aspects
Economic
International
National
Regional
Local


Internal Issues
Organization Culture
Relationship with internal stake holders
Governance
Decision making process
Organizational Structure
Internal Issues
Process maturity
Current Roles & Resp.
Current system and tools
Strategy
Resource levels
Current capabilities

Clause 4.2 Understanding the needs & expectations of interested parties

Understanding needs and expectations due to their direct effect or potential effect on the organisation's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

Determine:

a. The interested parties that are relevant to FSMS;

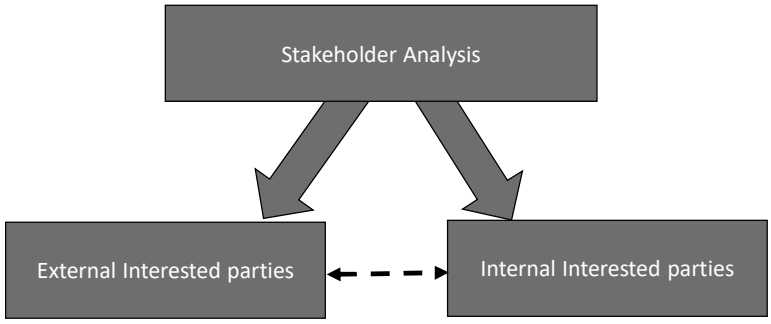
b. The requirements of these interested parties that are relevant to the FSMS.

- Legal requirements
- Regulatory requirements
- Contractual obligations 4.Other requirements identified by organization

Clause 4.2 Understanding the needs & expectations of interested parties ….cont.

- Update such determinations in order to understand and anticipate the needs or expectations affecting customer requirements and customer satisfaction.
- Addressing current and anticipated future needs lead to improvement and innovation opportunities.
- Monitor and review the information about these interested parties and relevant requirements

Clause 4.2 Understanding the needs & expectations of interested parties ….cont.



Clause 4.2 Understanding the needs & expectations of interested parties (Continue)

Interested parties:

Consider the following relevant interested parties:

a) Direct customers

b) End users;

c) Suppliers, distributors, retailers or others involved in the supply chain

d) Regulators and Govt. Organization

e) Any other relevant interested parties.

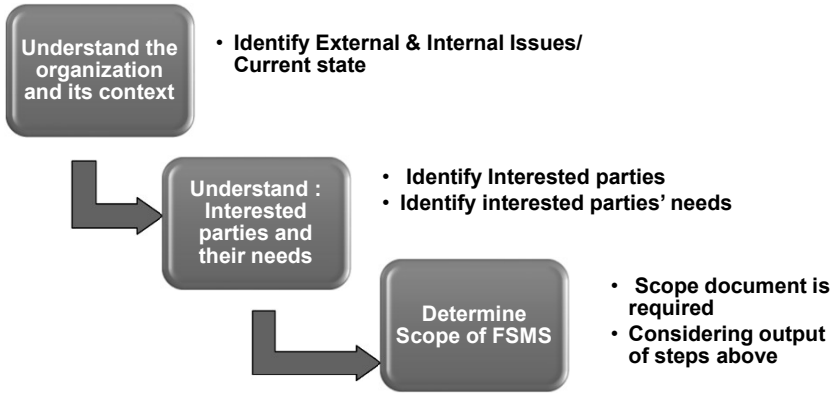
Exercise 2: Identification of the External & Internal Issues, Interested Parties and their needs and expectations

Clause 4.3 Determining the scope of the quality management system

Determine the boundaries and applicability of the FSMS to establish its scope.
When determining this scope, consider:
a. The external and internal issues (4.1);
b. The requirements of relevant interested parties (4.2);
c. The products and services of the organization.

The scope is available and maintained as documented information stating the:
• Type of products, processes, services and production site covered by the FSMS.

Approach- 4.1 to 4.3: Step Zero



4.4 Establishment of Food Safety Management System (FSMS)

- Identify processes
- Determine the inputs and outputs
- Ensure the necessary resources are provided
- Assigning responsibility and authority
- Continually improve the processes.

Include the processes needed and their interactions in accordance with the requirements of ISO 9001:2015 standard

5.0 Leadership

5.1 Leadership and commitment

5.2 Policy

5.3 Organizational roles, responsibilities and authorities

Clause 5.1 Leadership and Commitment

5.1.1 General

Top management Demonstrate leadership & commitment for FSMS by:

a) Taking accountability of the effectiveness of the QMS;

b) Ensuring that the quality policy and quality objectives are established for QMS and are compatible with the strategic direction and the context of the organization;

c) Integration of QMS requirements in to Organization's business processes

d) Promoting awareness of the process approach and risk based thinking;

e) Ensuring that the resources needed for QMS are available;

5.1.1 General ……..cont.

a) Communicating the importance of effective Quality management and of conforming to QMS requirements;

b) Ensuring that the QMS achieves its intended results;

c) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

d) Promoting improvement;

e) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Clause 5.1.2 Customer Focus

Top management demonstrate leadership and commitment with respect to customer focus by ensuring that:

a. Customer requirements and applicable statutory and regulatory requirements are determined, understood and met;

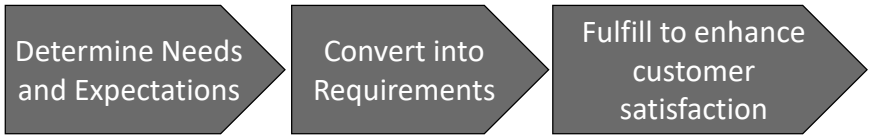
b. The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c. The focus on enhancing customer satisfaction is maintained.

Clause 5.1.2 Customer Focus (Continue…)

- Top management must ensure that customer requirements are:

- **Determined**
- **Met to enhance customer satisfaction**



Clause 5.2 Food Safety Policy

5.2.1 Establishing the food safety policy

Establish, review and maintain a quality policy by top management that:

a. Is appropriate to the purpose & context of the organization;
b. Provides a framework for setting & reviewing Food Safety objectives;
c. Includes a commitment to satisfy applicable requirements;
d. Includes a commitment to improvement of FSMS.
e. addresses the need to ensure competencies related to food safety.

Clause 5.2 Food Safety Policy

5.2.1 Establishing the food safety policy

5.2.2 Communicating the Food Safety Policy

The policy shall be :

a. Available and maintained as documented information;

b. Communicated, understood and applied within the organization;

c. Available and accessible to relevant interested parties, as appropriate.

Clause 5.3 Organizational roles, responsibilities and authorities

Top management ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Clause 5.3 Organizational roles, responsibilities and authorities

Assign the responsibility & authority for:

a. **ensuring that the FSMS conforms to the requirements of this document;**
b. **reporting on the performance of the FSMS to top management;**
c. **appointing the food safety team and the food safety team leader;**
d. **designating persons with defined responsibility and authority to initiate and document action(s).**

Clause 5.3 Organizational roles, responsibilities and authorities

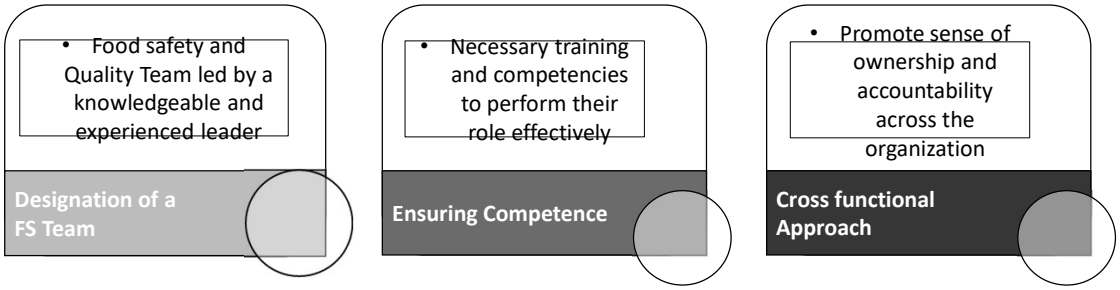
The food safety team leader shall be responsible for:

a. **ensuring the FSMS is established, implemented, maintained and updated;**
b. **managing and organizing the work of the food safety team;**
c. **ensuring relevant training and competencies for the food safety team**
d. **reporting to top management on the effectiveness and suitability of the FSMS.**

All persons shall have the responsibility to :

a. report problem(s) with regards to the FSMS to identified person(s).

Clause 5.3 Organizational roles, responsibilities and authorities



Clause 5.3 Organizational roles, responsibilities and authorities

Building and maintaining a food safety and Quality Culture

How to build this culture……..?

- Clear communication
- Training and resources
- Employee engagement

Clause 5.3 Organizational roles, responsibilities and authorities

Tools

- Training Program
- Internal Audit and Review
- Communication Platforms
- Resource Management Systems
- Employee engagement initiatives

By following the outlined responsibilities and leveraging the right tools, an organization can build a robust FSMS That not only complies with the standard but also ensures the production of safe, high-quality food products.

6.0 Planning

6 Planning

6.1 Actions to address risks and opportunities

6.2 Food Safety objectives and planning to achieve them

6.3 Planning of changes

EXERCISE-3

PLANNING PROCESS

RISK BASED THINKING

RISK : "Effect of uncertainty"

- Note 1 : An effect is a deviation from the expected - positive or negative
- Note 2 : Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
- Note 3: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:2009, 478 3.5.1.3) and "consequences" (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

RISK BASED THINKING

- Note 4 : Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.
- Note 5: The term "risk" is sometimes used when there is only the possibility of negative consequences

Opportunity

"A favorable situation to getting and intended result. It may be taken or not"

RISK BASED THINKING

ISO 31000:

'the threat or possibility that an action or element will adversely or beneficially affect an organizations ability to achieve its objectives'

COMMON RISK

- Product/service failure risk
- Public Health Risk
- Product spoilage Risk
- Process failure risk
- IT failure risk
- IT security risk
- Low productivity & yield
- Lack of competence
- Failure of suppliers
- Resource shortage risk
- Customer dissatisfaction risk

RISK BASED THINKING & FSMS

The concept of risk in the context of the ISO 22000 standard is limited to events and their consequences relating to the performance and effectiveness of the FSMS. Public authorities are responsible for addressing public health risks. Organizations are required to manage food safety hazards and the requirements related to this process .

RISK BASED THINKING & FSMS

Actions should be taken to mitigate risks.

For example;

- Change in supplier when raw materials are consistently not meeting requirements
- Risk of employees with specific skills leaving the company
- Monitoring of legal requirements, to not be caught unaware of change

RISK BASED THINKING & QMS

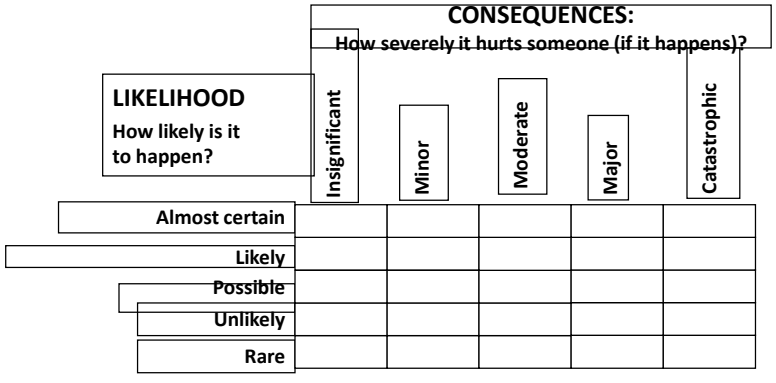
- ISO 22000:2018 requires a systematic approach to risk quantification
- Quantitative or qualitative approach, or their blend
- When selecting methodology always consider the risk of delivering non-conforming products/ services

For further guidance refer ISO 31000 & ISO 31010

ISSUES, R&O EXAMPLE

Issues	Expected Results	Risk	Opportunity
Availability of reliable, qualified and competent workforce (internal)	Workforce is competent	Existing workforce not skilled in installation work	Opportunity to multi-skill installation team
Competitors - cease trading (external)	We take on their contacts	Have we the means to do this?	Create plans for rapid expansion (workshop, infrastructure etc.)

Risk Analysis



RISK/ OPPORTUNITY ANALYSIS SHEET

R&O RELATED CLAUSES

- 4.4.1 f - Addressing risk & opportunities (R&O) for each of QMS processes
- 5.1.1 d - Top Management promoting the use of process approach & risk based thinking (RBT)
- 5.1.2b - For customer focus top management to ensure R&O that can effect conformity of products & services and ability to enhance customers satisfaction are determined and addressed
- 6.1.1- When planning FSMS, the organization to determine R&O that need to be addressed

R&O RELATED CLAUSES

- 6.1.2- The organization shall plan action to address R&O
- 8.1 - Plan, implement & control the processes relating to provision of product & services and implement actions determined for R&O
- 9.3.1 e - The results of analysis shall be used to evaluate the effectiveness of actions taken to address R&O
- 9.3.2e - Effectiveness of actions taken to address R&O as an input to management review
- 10.2.1 e - After corrective action update R&O determine during planning, if necessary

6.1 Actions to address risks and opportunities

Avoiding Risks	Taking Risks for Opportunities	Elimination Risks source
Changing livelihood or Consequences	Sharing Risks	Accepting Risks

Clause 6.2 Food Safety (FS) Objectives & Planning to achieve them

6.2.1 Establish objectives for the FSMS at relevant functions and levels.

The food safety objectives :

- **consistent with the FS policy,**
- **measurable;**
- **take into account applicable requirements;**
- **relevant to conformity of products and services and the enhancement of customer satisfaction;**
- **monitored;**
- **communicated;**
- **updated as appropriate**

Retain as documented information on the objectives for the FSMS.

Objectives

- To market innovative, reliable, consistent and cost effective products,
- To render genuine quality and safety to satisfy need of customer,
- To provide unparalleled service to match the expectation of the customer,
- To protect public health and environment with commitment,
- Continually improve the effectiveness of food safety management system.

6.2 Objectives of the food safety management system and planning to achieve them

Sample Quantifiable Objectives

Quantifiable Objectives for 2025	
Parameters	**Annual Target**
• **To reduce the incidence of foreign material (e.g., plastic, metal, glass) in finished products within the next 12 months, as measured by customer complaints and internal checks. (Specific, Measurable, Time-bound, Relevant)**	**by 50%**
• **To ensure compliance with critical control point (CCP) monitoring frequencies and critical limits as defined in the HACCP plan, verified through daily records.** (Specific, Measurable, Relevant)	**100%**
• **To reduce the number of customer complaints related to food safety by in the current year.** (Specific, Measurable, Time-bound, Relevant)	**20%**
• **To achieve completion of food safety induction training for new employees before job commencement.** (Specific, Measurable, Relevant)	**100%**

Clause 6.2 Food Safety (FS) Objectives & Planning to achieve them

6.2.2 Planning how to achieve the FSMS objectives, shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

Prepare Objectives achievement plan

Clause 6.3 Planning of Changes

Determines the needs and opportunities for change to the FSMS and the change are carried out and communicated in a planned and systematic manner.

Consider:

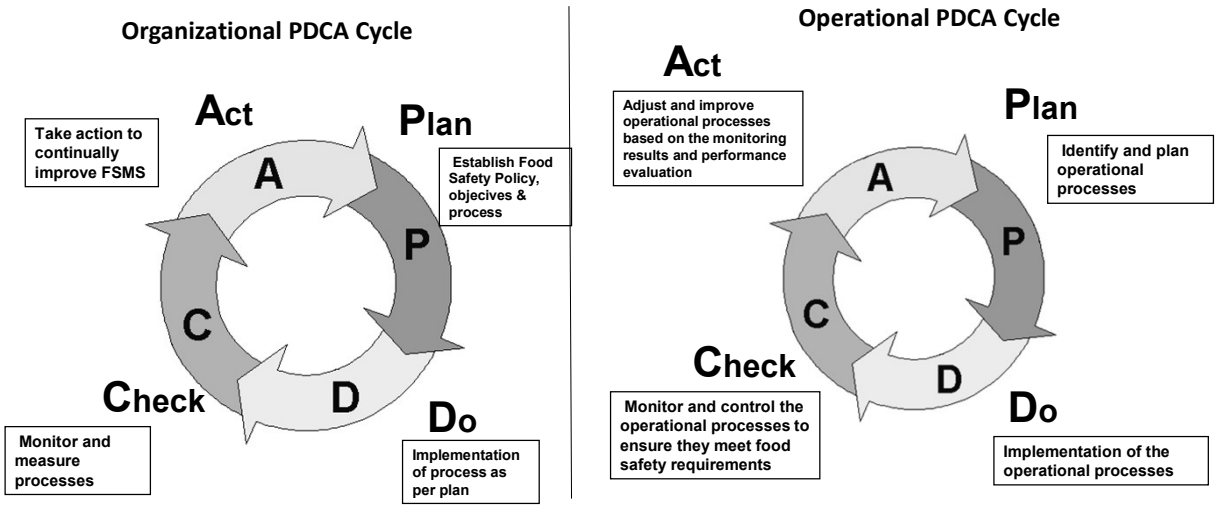
a) The purpose of the change and their potential consequences;

b) the continued integrity of the FSMS;

c) The availability of resources;

d) The allocation or reallocation of responsibilities and authorities.

2 PDCA Cycles



EXERCISE-4

DETERMINING RISKS AND OPPORTUNITIES

7.0 Support

7.0 Support

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

Clause 7.1 Resources

7.1.1 General

Determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the food safety management system

Consider;

a. the capability of, and any constraints on, existing internal resources;

b. the need for external resources.

7.1.2 People

• The organization shall ensure that persons necessary to operate and maintain an effective FSMS are competent

Clause 7.1 Resources

7.1.2 People

• The organization shall ensure that persons necessary to operate and maintain an effective FSMS are competent

•Where the assistance of external experts is used for the development, implementation, operation or assessment of the FSMS, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information.

Clause 7.1 Resources (Continue)

7.1.3 Infrastructure

The organization shall provide the resources for the determination, establishment and maintenance of

the infrastructure necessary to achieve conformity with the requirements of the FSMS.

Infrastructure can include:

- **land, vessels, buildings and associated utilities;**
- **equipment, including hardware and software;**
- **transportation;**
- **information and communication technology**

Clause 7.1 Resources (Continue)

7.1.4 Work environment

The organization shall determine, provide and maintain the resources for the establishment, management and maintenance of the work environment necessary to achieve conformity with the requirements of the FSMS.

Suitable environment can be a combination of human and physical factors, such as:

•social (e.g. non-discriminatory, non-confrontational);
•psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
• physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

Clause 7.1 Resources (Continue)

Few Examples:

Clean room,
Controlled temperature,
Anti-static precautions,
Hygiene controls, etc.

The conditions under which work is performed includes physical environment and other factors such as noise, temperature, humidity, lighting and weather etc.

Clause 7.1 Resources (continue)

7.1.5 Externally developed elements of the food safety management system

When an organization establishes, maintains, updates and continually improves its FSMS by using externally developed elements of a FSMS, including PRPs, the hazard analysis and the hazard control plan, the organization shall ensure that the provided elements are:

a. developed in conformance with requirements of this document;

b. applicable to the sites, processes and products of the organization;

c. specifically adapted to the processes and products of the organization by the food safety team;

d. implemented, maintained and updated as required by this document;

e. retained as documented information

Clause 7.1 Resources (continue)

7.1.6 Control of externally provided processes, products or services

The organization shall:

a. establish and apply criteria for the evaluation, selection, monitoring of performance and reevaluation of external providers of processes, products and/or services;

b. ensure adequate communication of requirements to the external provider(s);

c. ensure that externally provided processes, products or services do not adversely affect the organization's ability to consistently meet the requirements of the FSMS;

d. retain documented information of these activities and any necessary actions as a result of the evaluations and re-evaluations.

Clause 7.2 Competence

The organization shall:

a. determine the necessary competence of person(s), including external providers, doing work under its control that affects its food safety performance and effectiveness of the FSMS;

b. ensure that these persons, including the food safety team and those responsible for the operation of the hazard control plan, are competent on the basis of appropriate education, training and/or experience;

c. ensure that the food safety team has a combination of multi-disciplinary knowledge and experience in developing and implementing the FSMS (including, but not limited to, the organization's products, processes, equipment and food safety hazards within the scope of the FSMS);

d. where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

e. retain appropriate documented information as evidence of competence.

Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

Clause 7.3 Awareness

Ensure persons doing work under the organization's control are aware of:

a. The food safety policy;
b. the objectives of the FSMS relevant to their task(s);
c. their individual contribution to the effectiveness of the FSMS, including the benefits of improved food safety performance;
d. the implications of not conforming with the FSMS requirements.

Clause 7.4 Communication

Determine the internal and external communication relevant to the FSMS including:

a. On what it will communicate;
b. When to communicate;
c. With whom to communicate;
d. How to communicate;
e. Who communicates

Preferably prepare the communication plan

Clause 7.5 Documented Information

7.5.1 General

Food Safety Management System shall include:

a. Documented information required;

b. Documented information determined by the organization as being necessary for the effectiveness of the FSMS

c. documented information and food safety requirements required by statutory, regulatory authorities and customers.

The extent of documented information for a FSMS can differ from one organization to another due to:

a) The size of organization and its type of activities, processes, products and services;

b) The complexity of processes and their interactions;

c) The competence of persons.

Clause 7.5 Documented Information (continue)

7.5.2 Creating and updating

When creating and updating documented information ensure :

a. Identification and description (e.g. a title, date, author, or reference number);

b. Format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c. Review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the FSMS to be controlled to ensure:

a) It is available and suitable for use, where and when it is needed;

b) It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

Clause 7.5 Documented Information

7.5.3 Control of documented information (Continue)

7.5.3.2 For the control of documented information, the organization include the following activities, as applicable:

a) Distribution, access, retrieval and use;

b) Storage and preservation, including preservation of legibility;

c) Control of changes (e.g. version control);

d) Retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the QMS and identified as appropriate, and controlled.

Sample list of documented information

Sample list of documented information required for FSMS

a) Documented statements of the Food Safety policy and FSMS objectives

b) The scope of the FSMS and information to support the operation of the processes

c) Risk assessment report

d) Design and development inputs, controls and output

e) Calibration records for fitness of monitoring and measurement resources

f) Records for compliance to this FSMS standard requirements

g) Internal audit records

h) Management review minutes

8.0 Operation

8.1 Operational planning and control

8.2 Prerequisite programmes (PRPs)

8.3 Traceability system

8.4 Emergency preparedness and response

8.5 Hazard control

8.6 Updating the information specifying the PRPs and the hazard control plan

8.7 Control of monitoring and measuring

8.8 Verification related to PRPs and the hazard control plan

8.9 Control of product and process nonconformities

Clause 8.1 Operational Planning and Control

Plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products, and to implement the actions by:

a. establishing criteria for the processes;

b. implementing control of the processes in accordance with the criteria;

c. keeping documented information to the extent necessary to have the confidence to demonstrate that the processes have been carried out as planned.

Clause 8.1 Operational Planning and Control

Control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

Ensure that outsourced processes are controlled

Clause 8.2 Prerequisite programmes (PRPs)

8.2.1:Organization shall establish, implement, maintain and update PRP(s) to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment.

8.2.2:The PRP(s) shall be:

a. appropriate to the organization and its context with regard to food safety;

b. appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled;

c. implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or process

d. approved by the food safety team.

Clause 8.2 Prerequisite programmes (PRPs)

8.2.3: **When selecting and/or establishing PRP(s), the organization shall ensure that applicable statutory, regulatory and mutually agreed customer requirements are identified.**

The organization should consider:

a. the applicable part of the ISO/TS 22002 series;

b. applicable standards, codes of practice and guidelines.

Clause 8.2 Prerequisite programmes (PRPs)

8.2.4: **When establishing PRP(s) the organization shall consider:**

a. construction, lay-out of buildings and associated utilities;

b. lay-out of premises, including zoning, workspace and employee facilities;

c. supplies of air, water, energy and other utilities;

d. pest control, waste and sewage disposal and supporting services;

e. the suitability of equipment and its accessibility for cleaning and maintenance;

f. supplier approval and assurance processes (e.g. raw materials, ingredients, chemicals and packaging);.

Clause 8.2 Prerequisite programmes (PRPs)

8.2.4: When establishing PRP(s) the organization shall consider:

g. reception of incoming materials, storage, dispatch, transportation and handling of products;

h. measures for the prevention of cross contamination;

i. cleaning and disinfecting;

j. personal hygiene;

k. product information/consumer awareness;

l. others, as appropriate.

Documented information shall specify the selection, establishment, applicable monitoring and verification of the PRP(s).

Clause 8.3 Traceability system

The traceability system shall be able to uniquely identify incoming material from the suppliers and the first stage of the distribution route of the end product. When establishing and implementing the traceability system, the following shall be considered as a minimum:

a) relation of lots of received materials, ingredients and intermediate products to the end products;

b) reworking of materials/products;

c) distribution of the end product.

The organization shall ensure that applicable statutory, regulatory and customer requirements are identified.

Clause 8.3 Traceability system

Documented information as evidence of the traceability system shall be retained for a defined period to include, as a minimum, the shelf life of the product. The organization shall verify and test the effectiveness of the traceability system.

Where appropriate, the verification of the system is expected to include the reconciliation of quantities

of end products with the quantity of ingredients as evidence of effectiveness.

The organization shall ensure that applicable statutory, regulatory and customer requirements are identified.

Clause 8.4 Emergency preparedness and response

8.4.1 General

Top management shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety which are relevant to the role of the organization in the food chain.

Documented information shall be established and maintained to manage these situations and incidents.

Clause 8.4 Emergency preparedness and response

8.4.2 Handling of emergencies and incidents

The organization shall:

b) take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident and the potential food safety impact;

c) periodically test procedures where practical;

Clause 8.4 Emergency preparedness and response

8.4.2 Handling of emergencies and incidents

d) review and, where necessary, update the documented information after the occurrence of anyincident, emergency situation or tests.

Examples of emergency situations that can affect food safety and/or production are natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents, e.g. interruption of essential services such as water, electricity or refrigeration supply.

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.1 General

To carry out the hazard analysis, preliminary documented information shall be collected, maintained and updated by the food safety team. This shall include, but not be limited to:

a. applicable statutory, regulatory and customer requirements;

b. the organization's products, processes and equipment;

c. food safety hazards relevant to the FSMS.

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials

The organization shall ensure that all applicable statutory and regulatory food safety requirements are identified for all raw materials, ingredients and product contact materials. a. applicable statutory, regulatory and customer requirements;

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials

The organization shall maintain documented information concerning all raw materials, ingredients and product contact materials to the extent needed to conduct the hazard analysis, including the following, as appropriate:

a. biological, chemical and physical characteristics;

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials

b) composition of formulated ingredients, including additives and processing aids;

c) source (e.g. animal, mineral or vegetable);

d) place of origin (provenance);

e) method of production;

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials

f. method of packaging and delivery;

g. storage conditions and shelf life;

h. preparation and/or handling before use or processing;

i. acceptance criteria related to food safety or specifications of purchased materials and ingredients appropriate to their intended use.

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.3 Characteristics of end products

All applicable statutory and regulatory food safety requirements are identified for all the end products intended to be produced

The organization shall maintain documented information concerning the characteristics of end products to the extent needed to conduct the hazard analysis.

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.3 Characteristics of end products

The documented information include on the following, as appropriate:

a) product name or similar identification;

b) composition;

c) biological, chemical and physical characteristics relevant for food safety;

d) intended shelf life and storage conditions;

e) packaging;

f) labelling relating to food safety and/or instructions for handling, preparation and intended use;

g) method(s) of distribution and delivery.

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.4 Intended use

The intended use, including reasonably expected handling of the end product

and any unintended use but reasonably expected mishandling and misuse of the end product, shall be considered and shall be maintained as documented information to the extent needed to conduct the hazard analysis

***Where appropriate, groups of consumers/users shall be identified for each product.**

***Groups of consumers/users known to be especially vulnerable to specific food safety hazards shall be identified.**

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.1 Preparation of the flow diagrams

The food safety team shall establish, maintain and update flow diagrams as documented information for the products or product categories and the processes covered by the FSMS.

Flow diagrams provide a graphic representation of the process. Flow diagrams shall be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of food safety hazards.

Exercise 5: Construct a Flow diagram

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.1 Preparation of the flow diagrams

It shall be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams shall, as appropriate, include the following:

a) the sequence and interaction of the steps in the operation;

b) any outsourced processes;

c) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;

d) where reworking and recycling take place;

e) where end products, intermediate products, by-products and waste are released or removed.

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.2 On-site confirmation of flow diagrams

The food safety team shall confirm on-site the accuracy of the flow diagrams, update the flow diagrams

where appropriate and retain as documented information.

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.3 Description of processes and process environment

The food safety team shall describe, to the extent needed to conduct the hazard analysis:

a) the layout of premises, including food and non-food handling areas;

b) processing equipment and contact materials, processing aids and flow of materials;

Clause 8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.3 Description of processes and process environment

c) existing PRPs, process parameters, control measures (if any) and/or the strictness with which theyare applied, or procedures that can influence food safety;

d) external requirements (e.g. from statutory and regulatory authorities or customers) that can impact the choice and the strictness of the control measures.

The variations resulting from expected seasonal changes or shift patterns shall be included as appropriate.

The descriptions shall be updated as appropriate and maintained as documented information.

Exercise 6: Hazard Assessment

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.1 General

The food safety team shall conduct a hazard analysis, based on the preliminary information, to determine the hazards that need to be controlled. The degree of control shall ensure food safety and, where appropriate, a combination of control measures shall be used.

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.2 Hazard identification and determination of acceptable levels

8.5.2.2.1 The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment.

The identification shall be based on:

a) the preliminary information and data collected;

b) experience;

c) internal and external information including, to the extent possible, epidemiological, scientific and other historical data;

d) information from the food chain on food safety hazards related to the safety of the end products, intermediate products and the food at the time of consumption;

e) statutory, regulatory and customer requirements.

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.2 Hazard identification and determination of acceptable levels

8.5.2.2.2 The organization shall identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist.

When identifying hazards, the organization shall consider:

a) the stages preceding and following in the food chain;

b) all steps in the flow diagram;

c) the process equipment, utilities/services, process environment and persons.

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.2 Hazard identification and determination of acceptable levels

8.5.2.2.3 The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible.

When determining acceptable levels, the organization shall:

a) ensure that applicable statutory, regulatory and customer requirements are identified;

b) consider the intended use of end products;

c) consider any other relevant information.

The organization shall maintain documented information concerning the determination of acceptable levels and the justification for the acceptable levels.

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.3 Hazard assessment

The organization shall conduct, for each identified food safety hazard, a hazard assessment to determine whether its prevention or reduction to an acceptable level is essential.

The organization shall evaluate each food safety hazard with regard to:

a) the likelihood of its occurrence in the end product prior to application of control measures;

b) the severity of its adverse health effects in relation to the intended use.

The organization shall identify any significant food safety hazards.

The methodology used shall be described, and the result of the hazard assessment shall be maintained as documented information.

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.4 Selection and categorization of control measure(s)

8.5.2.4.1 Based on the hazard assessment, the organization shall select an appropriate control

measure or combination of control measures that will be capable of preventing or reducing the identified

significant food safety hazards to defined acceptable levels.

The organization shall categorize the selected identified control measure(s) to be managed as OPRP(s) or at CCPs.

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.4 Selection and categorization of control measure(s)

The categorization shall be carried out using a systematic approach. For each of the control measures selected, there shall be an assessment of the following:

a) the likelihood of failure of its functioning;

b) the severity of the consequence in the case of failure of its functioning; this assessment shall include:

1) the effect on identified significant food safety hazards;

2) the location in relation to other control measure(s);

3) whether it is specifically established and applied to reduce the hazards to an acceptable level;

4) whether it is a single measure or is part of combination of control measure(s).

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.4 Selection and categorization of control measure(s)

8.5.2.4.2 In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of:

a) establishing measurable critical limits and/or measurable/observable action criteria;

b) monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;

c) applying timely corrections in case of failure.

Clause 8.5 Hazard control

8.5.2 Hazard analysis

8.5.2.4 Selection and categorization of control measure(s)

The decision-making process and results of the selection and categorization of the control measures shall be maintained as documented information.

External requirements (e.g. statutory, regulatory and customer requirements) that can impact the choice and the strictness of the control measures shall also be maintained as documented information.

Clause 8.5 Hazard control

8.5.3 Validation of control measure(s) and combinations of control measures

The food safety team shall validate that the selected control measures are capable of achieving the intended control of the significant food safety hazard(s). This validation shall be done prior to implementation of control measure(s) and combinations of control measures to be included in the hazard control plan and after any change therein.

When the result of validation shows that the control measures(s) is (are) not capable of achieving the intended control, the food safety team shall modify and re-assess the control measure(s) and/or combination(s) of control measure(s).

Clause 8.5 Hazard control

8.5.3 Validation of control measure(s) and combinations of control measures

The food safety team shall maintain the validation methodology and evidence of capability of the control measure(s) to achieve the intended control as documented information.

Modification can include changes in control measure(s) (i.e. process parameters, rigour and/or their combination) and/or change(s) in the manufacturing technologies for raw materials, end product characteristics,methods of distribution and intended use of the end products.

Clause 8.5 Hazard control

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.1 General

Establish, implement and maintain a hazard control plan. The hazard control plan shall be maintained as documented information and shall include the following information for each control measure at each CCP or OPRP:

a) food safety hazard(s) to be controlled at the CCP or by the OPRP;

b) critical limit(s) at CCP or action criteria for OPRP;

c) monitoring procedure(s);

d) correction(s) to be made if critical limits or action criteria are not met;

e) responsibilities and authorities;

f) records of monitoring.

Clause 8.5 Hazard control

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.2 Determination of critical limits and action criteria

Critical limits at CCPs and action criteria for OPRPs shall be specified. The rationale for their determination shall be maintained as documented information.

Critical limits at CCPs shall be measurable. Conformance with critical limits shall ensure that the acceptable level is not exceeded.

Action criteria for OPRPs shall be measurable or observable. Conformance with action criteria shall contribute to the assurance that the acceptable level is not exceeded.

Clause 8.5 Hazard control

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.3 Monitoring systems at CCPs and for OPRPs

At each CCP, a monitoring system shall be established for each control measure or combination of control measure(s) to detect any failure to remain within the critical limits. The system shall include all scheduled measurements relative to the critical limit(s).

For each OPRP, a monitoring system shall be established for the control measure or combination of control measure(s) to detect failure to meet the action criterion.

Clause 8.5 Hazard control

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.3 Monitoring systems at CCPs and for OPRPs

The monitoring system, at each CCP and for each OPRP, shall consist of documented information, including:

a) measurements or observations that provide results within an adequate time frame;

b) monitoring methods or devices used;

c) applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations;

d) monitoring frequency;

e) monitoring results;

f) responsibility and authority related to monitoring;

g) responsibility and authority related to evaluation of monitoring results.

Clause 8.5 Hazard control

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.3 Monitoring systems at CCPs and for OPRPs

At each CCP, the monitoring method and frequency shall be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product.

For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.

When monitoring an OPRP is based on subjective data from observations (e.g. visual inspection), the method shall be supported by instructions or specifications.

Clause 8.5 Hazard control

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.4 Actions when critical limits or action criteria are not met

The organization shall specify corrections and corrective to be taken when critical limits or action criterion are not met and shall ensure that:

a) the potentially unsafe products are not released;

b) the cause of nonconformity is identified;

c) the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria;

d) recurrence is prevented.

The organization shall make corrections and corrective actions.

Exercise 7: HACCP Plan

Clause 8.5 Hazard control

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.5 Implementation of the hazard control plan

The organization shall implement and maintain the hazard control plan, and retain evidence of the implementation as documented information.

Clause 8.6 Updating the information specifying the PRPs and the hazard control plan

Following the establishment of the hazard control plan, the the following information need to be updated, if necessary:

a) characteristics of raw materials, ingredients and product-contact materials;

b) characteristics of end products;

c) intended use;

d) flow diagrams and descriptions of processes and process environment.

The organization shall ensure that the hazard control plan and/or the PRP(s) are up to date.

Clause 8.7 Control of monitoring and measuring

Provide evidence that the specified monitoring and measuring methods and equipment in use are adequate for the monitoring and measuring activities related to the PRP(s) and the hazard control plan.

The monitoring and measuring equipment used shall be:

a) calibrated or verified at specified intervals prior to use;

b) adjusted or re-adjusted as necessary;

c) identified to enable the calibration status to be determined;

d) safeguarded from adjustments that would invalidate the measurement results;

e) protected from damage and deterioration.

The results of calibration and verification shall be retained as documented information. The calibration of all the equipment shall be traceable to international or national measurement standards.

Clause 8.8 Verification related to PRPs and the hazard control plan

Establish, implement and maintain verification activities. The verification planning shall define purpose, methods, frequencies and responsibilities for the verification activities.

The verification activities shall confirm that:

a) the PRP(s) are implemented and effective;

b) the hazard control plan is implemented and effective;

c) hazard levels are within identified acceptable levels;

d) input to the hazard analysis is updated;

e) other actions determined by the organization are implemented and effective.

Clause 8.8 Verification related to PRPs and the hazard control plan

8.8.1 Verification

Ensure that verification activities are not carried out by the person responsible for monitoring the same activities.

Verification results shall be retained as documented information and shall be communicated.

Where verification is based on testing of end product samples or direct process samples and where such test samples show nonconformity with the acceptable level of the food safety hazard, the organization shall handle the affected lot(s) of product as potentially unsafe and apply corrective actions.

8.8.2 Analysis of results of verification activities

The food safety team shall conduct an analysis of the results of verification that shall be used as an input to the performance evaluation of the FSMS

Clause 8.9 Control of product and process nonconformities

8.9.1 General

Ensure that data derived from the monitoring of OPRPs and at CCPs are evaluated by designated persons who are competent and have the authority to initiate corrections and corrective actions.

8.9.2 Corrections

8.9.2.1 Ensure that when critical limits at CCP(s) and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release.

Establish, maintain and update documented information that includes:

a) a method of identification, assessment and correction for affected products to ensure their proper handling;

b) arrangements for review of the corrections carried out.

Clause 8.9 Control of product and process nonconformities

8.9.2 Corrections

8.9.2.2 When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products

8.9.2.3 Where action criteria for an OPRP are not met, the following shall be carried out:

a) determination of the consequences of that failure with respect to food safety;

b) determination of the cause(s) of failure;

c) identification of the affected products and handling as potentially unsafe products.

The organization shall retain results of the evaluation as documented information.

Clause 8.9 Control of product and process nonconformities

8.9.2 Corrections

8.9.2.4 Documented information shall be retained to describe corrections made on nonconforming products and processes, including:

a) the nature of the nonconformity;

b) the cause(s) of the failure;

c) the consequences as a result of the nonconformity.

Clause 8.9 Control of product and process nonconformities

8.9.3 Corrective actions

The need for corrective actions shall be evaluated when critical limits at CCP(s) and/or action criteria for OPRPs are not met.

The organization shall establish and maintain documented information that specifies appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to return the process to control after a nonconformity is identified.

Clause 8.9 Control of product and process nonconformities

8.9.4 Handling of potentially unsafe products

8.9.4.1 General

The organization shall take action(s) to prevent potentially unsafe products from entering the food chain, unless it can demonstrate that:

a) the food safety hazard(s) of concern is (are) reduced to the defined acceptable levels;

b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the food chain; or

c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

Clause 8.9 Control of product and process nonconformities

8.9.4 Handling of potentially unsafe products

8.9.4.1 General

The organization shall retain products that have been identified as potentially unsafe under its control until the products have been evaluated and the disposition has been determined.

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal/recall.

The controls and related responses from relevant interested parties and authorization for dealing with potentially unsafe products shall be retained as documented information.

Clause 8.9 Control of product and process nonconformities

8.9.4 Handling of potentially unsafe products

8.9.4.2 Evaluation for release

Each lot of products affected by the nonconformity shall be evaluated.

Products affected by failure to remain within critical limits at CCPs shall not be released, but shall be handled in accordance with 8.9.4.3.

Products affected by failure to meet action criterion for OPRPs shall only be released as safe when any of the following conditions apply:

a) evidence other than the monitoring system demonstrates that the control measures have been effective;

Clause 8.9 Control of product and process nonconformities

8.9.4 Handling of potentially unsafe products

8.9.4.2 Evaluation for release

b) evidence shows that the combined effect of the control measures for that particular product conforms to the performance intended (i.e. identified acceptable levels);

c) the results of sampling, analysis and/or other verification activities demonstrate that the affected products conform to the identified acceptable levels for the food safety hazard(s) concerned.

Results of evaluation for release of products shall be retained as documented information.

Clause 8.9 Control of product and process nonconformities

8.9.4 Handling of potentially unsafe products

8.9.4.3 Disposition of nonconforming products

Products that are not acceptable for release shall be:

a) reprocessed or further processed within or outside the organization to ensure that the food safety hazard is reduced to acceptable levels; or

b) redirected for other use as long as food safety in the food chain is not affected; or

c) destroyed and/or disposed as waste.

Documented information on the disposition of nonconforming products, including the identification of the person(s) with approving authority shall be retained.

Clause 8.9 Control of product and process nonconformities

8.9.5 Withdrawal/recall

Ensure the timely withdrawal/recall of lots of end products that have been identified as potentially unsafe, by appointing competent person(s) having the authority to initiate and carry out the withdrawal/recall.

Establish and maintain documented information for:

a) notifying relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers);

b) handling withdrawn/recalled products as well as products still in stock;

c) performing the sequence of actions to be taken.

Clause 8.9 Control of product and process nonconformities

8.9.5 Withdrawal/recall

Withdrawn/recalled products and end products still in stock shall be secured or held under the control of the organization until they are managed in accordance with 8.9.4.3.

The cause, extent and result of a withdrawal/recall shall be retained as documented information and reported to the top management as input for the management review.

The organization shall verify the implementation and effectiveness of withdrawals/recalls through the use of appropriate techniques (e.g. mock withdrawal/recall or practice withdrawal/recall) and retain documented information.

9.0 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review

Clause 9.1 Monitoring, measurement, analysis & evaluation

9.1.1 General

Determine :

a) What needs to be monitored & measured (M & M);

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the M & M shall be performed;

d) when the results from M & M shall be analysed and evaluated;

Evaluate the performance and the effectiveness of FSMS.

e) who shall analyse and evaluate the results from monitoring and measurement.

Retain appropriate documented information as evidence of the results.
Evaluate the performance and the effectiveness of the FSMS.

Clause 9.1 Monitoring, measurement, analysis & evaluation

9.1.2 Analysis and evaluation

Analyse and evaluate appropriate data and information arising from monitoring and measurement, including the results of verification activities related to PRPs and the hazard control plan the internal audits and external audits.

analysis shall be carried out:

a) to confirm that the overall performance of the system meets the planned arrangements and the

FSMS requirements established by the organization;

b) to identify the need for updating or improving the FSMS;

Clause 9.1 Monitoring, measurement, analysis & evaluation

9.1.2 Analysis and evaluation

c) to identify trends which indicate a higher incidence of potentially unsafe products or process failures;

d) to establish information for planning of the internal audit programme related to the status and importance of areas to be audited;

e) to provide evidence that corrections and corrective actions are effective.

The results of the analysis and the resulting activities shall be retained as documented information.

The results shall be reported to top management and used as input to the management review and the updating of the FSMS. Methods to analyse data can include statistical techniques.

Clause 9.2 Internal Audit

Conduct internal audits at planned intervals to provide information on whether the FSMS –

a. Conform to the organization's own FSMS requirements and the requirements of this international standard;

b. Is effectively implemented and maintained

The organization shall:

a. plan, establish, implement and maintain (an) audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes in the FSMS, and the results of monitoring, measurement and previous audits;

b. define the audit criteria and scope for each audit;

Clause 9.2 Internal Audit…….Cont.

c. select competent auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d. ensure that the results of the audits are reported to the food safety team and relevant management;

e. retain documented information as evidence of the implementation of the audit programme and the audit results;

Clause 9.2 Internal Audit…….Cont.

f. make the necessary correction and take the necessary corrective action within the agreed time frame;

g. determine if the FSMS meets the intent of the food safety policy and objectives of the FSMS.

Follow-up activities by the organization shall include the verification of the actions taken and the reporting of the verification results.

ISO 19011 provides guidelines for auditing management systems.

Clause 9.3 Management Review

9.3.1 Top management shall review the organization's FSMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

9.3.2 Management review inputs

The management review is planned and carried out taking into consideration:

a) The status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the FSMS, including changes in the organization and its context;

Clause 9.3 Management Review

c) information on the performance and the effectiveness of the FSMS, including trends in:

1) result(s) of system updating activities (see 4.4 and 10.3);
2) monitoring and measurement results;
3) analysis of the results of verification activities related to PRPs and the hazard control plan (see 8.8.2);
4) nonconformities and corrective actions;
5) audit results (internal and external);
6) inspections (e.g. regulatory, customer);
7) the performance of external providers;
8) the review of risks and opportunities and of the effectiveness of actions taken to address them;
9) the extent to which objectives of the FSMS have been met;

Clause 9.3 Management Review

d) the adequacy of resources;

e) any emergency situation, incident or withdrawal/recall that occurred;

f) relevant information obtained through external and internal communication, including requests and complaints from interested parties;

g) opportunities for continual improvement.

The data shall be presented in a manner that enables top management to relate the information to stated objectives of the FSMS.

Clause 9.3 Management Review output (Continued…)

The outputs of the management review shall include:

a) decisions and actions related to continual improvement opportunities;

b) any need for updates and changes to the FSMS, including resource needs and revision of the food safety policy and objectives of the FSMS.

Retain documented information as evidence of the results of management reviews. Include action taken in this information

10.0 Improvement

10 Improvement

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual Improvement

10.1 Nonconformity and corrective action

10.1.1 When a nonconformity occurs, the organization shall:

a) react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing the nonconformity;

2) determining the causes of the nonconformity;

3) determining if similar nonconformities exist, or could potentially occur;

10.1 Nonconformity and corrective action

10.1.1 When a nonconformity occurs, the organization shall:

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the FSMS, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Exercise 8: Non Conformity Report

Clause 10.2.2 Nonconformity & Corrective Action (Continue..)

10.1.2 Retain documented information as evidence of:

a. The nature of the Non Conformity and any subsequent actions taken;

b. The results of any corrective action.

Corrective action can reduce the likelihood of recurrence to an acceptable level.

Clause 10.2 Continual Improvement

Continually improvement of the suitability, adequacy, and effectiveness of the FSMS. Top management shall ensure that the organization continually improves the effectiveness of the FSMS through the use of

- **communication,**
- **management review,**
- **internal audit,**
- **analysis of results of verification activities,**
- **validation of control measure(s) and combination(s) of control measure(s),**
- **corrective actions and**
- **FSMS updating.**

Clause 10.3 Update of the food safety management system

Top management shall ensure that the FSMS is continually updated. To achieve this, the food safety team shall evaluate the FSMS at planned intervals. The team shall consider whether it is necessary to review the hazard analysis, the established hazard control plan and the established PRPs.

Clause 10.3 Update of the food safety management system

The updating activities shall be based on:

a) input from communication, external as well as internal;

b) input from other information concerning the suitability, adequacy and effectiveness of the FSMS;

c) output from the analysis of results of verification activities;

d) output from management review.

System updating activities shall be retained as documented information and reported as input to the management review.

Audit

Audit Programme

Audit Programme

Set of one or more audits planned for as specific a time frame and directed towards specific purpose

This includes:

- **Planning**
- **Organizing**
- **Conduct of the audit**
- **Objectives of the programme**
- **Extent of the programme (Scope)**
- **Audit Criteria**

PLAYERS IN THE AUDIT

- **Client**
- **Audit Team**
- **Auditee**

MANAGING AUDIT PROGRAMME

Task of the Audit Management:

- **Authority and responsibility**
- **Objectives and extent of the programme**
- **Resources**
- **Procedures**
- **Implementation**
- **Records**
- **Monitoring and review**

AUDIT ACTIVITIES

Task of the Audit Team

- **Initiating the audit**
- **Conducting Document Review**
- **Preparing for on-site audit activities**
- **Conducting the audit**
- **Preparing, approving and distributing the audit report**
- **Completing the audit**
- **Audit follow up**

AUDIT OBJECTIVES (ISO 19011:2018)

- ✓ **To evaluate capability of management system to ensure compliance with statutory, regulatory and contractual requirements**
- ✓ **To determine the effectiveness of the implemented management system in meeting specified objectives**
- ✓ **To determine the conformity or non conformity of the management system elements with specified requirements**
- ✓ **To identify areas for potential improvement of the management system**

AUDIT OBJECTIVES

Audit Programme Objectives : based on consideration of;

Management priorities

Commercial intentions

Management system requirements

Statutory, regulatory & contractual requirements

Need for supplier evaluation

Customer and other interested parties needs and requirements

Risks to the organization

FOOD SAFETY AUDIT TYPES

1st Party-WE are auditing our own system

(Internal)

2nd Party- WE are auditing another organization:

normally our supplier

(External)

3rd Party-WE are being audited by a certification/registration body

(External)

REASON FOR 1st PARTY AUDIT

- ✓Requirement of ISO 22000.2018
- ✓Monitors health of the system
- ✓ Source of information for use by management
- ✓ Powerful tool for continual improvement through
- ▪Employee involvement
- ▪Communication
- ▪Employee awareness, etc

REASON FOR 2nd PARTY AUDIT

Aids selection and grading of suppliers

Helps improve suppliers‘ food safety systems

Foundation for supplier partnerships

Aids deployment.

REASON FOR 3rd PARTY AUDIT

- ✓May reduce need for 2nd party audits
- ✓ Recognition of conformity to an international standard
- ✓ Contributes to reduction in avoidable costs to suppliers
- ✓Aids market competitiveness

Written Exam

INTERNATIONAL STANDARD

ISO 22000

Second edition
2018-06

Food safety management systems — Requirements for any organization in the food chain

Systèmes de management de la sécurité des denrées alimentaires — Exigences pour tout organisme appartenant à la chaîne alimentaire

Reference number
ISO 22000:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 17, *Management systems for food safety*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This second edition cancels and replaces the first edition (ISO 22000:2005), which has been technically revised through the adoption of a revised clause sequence. It also incorporates the Technical Corrigendum ISO 22000:2005/Cor.1:2006.

The following annexes are included to provide the users of this document with further information:

— Annex A: cross references between the CODEX HACCP principles and this document;

— Annex B: cross reference between this document and ISO 22000:2005.

Introduction

0.1 General

The adoption of a food safety management system (FSMS) is a strategic decision for an organization that can help to improve its overall performance in food safety. The potential benefits to an organization of implementing a FSMS based on this document are:

a) the ability to consistently provide safe foods and products and services that meet customer and applicable statutory and regulatory requirements;

b) addressing risks associated with its objectives;

c) the ability to demonstrate conformity to specified FSMS requirements.

This document employs the process approach (see 0.3), which incorporates the Plan-Do-Check-Act (PDCA) cycle (see 0.3.2) and risk-based thinking (see 0.3.3).

This process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its FSMS to deviate from the planned results, and to put in place controls to prevent or minimize adverse effects.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

"NOTES" provide guidance in understanding or clarifying the requirements in this document.

0.2 FSMS principles

Food safety is related to the presence of food safety hazards at the time of consumption (intake by the consumer). Food safety hazards can occur at any stage of the food chain. Therefore, adequate control throughout the food chain is essential. Food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a FSMS that combines the following generally recognized key elements:

— interactive communication;

— system management;

— prerequisite programmes;

— hazard analysis and critical control point (HACCP) principles.

In addition, this document is based on the principles that are common to ISO management system standards. The management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

This document adopts a process approach when developing and implementing a FSMS and improving its effectiveness to enhance production of safe products and services while meeting applicable requirements. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the food safety policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle, with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results.

The recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the food chain.

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be described briefly as follows:

Plan: establish the objectives of the system and its processes, provide the resources needed to deliver the results, and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where relevant) measure processes and the resulting products and services, analyse and evaluate information and data from monitoring, measuring and verification activities, and report the results;

Act: take actions to improve performance, as necessary.

In this document, and as illustrated in Figure 1, the process approach uses the concept of the PDCA cycle at two levels. The first covers the overall frame of the FSMS (Clause 4 to Clause 7 and Clause 9 to Clause 10). The other level (operational planning and control) covers the operational processes within the food safety system as described in Clause 8. Communication between the two levels is therefore essential.

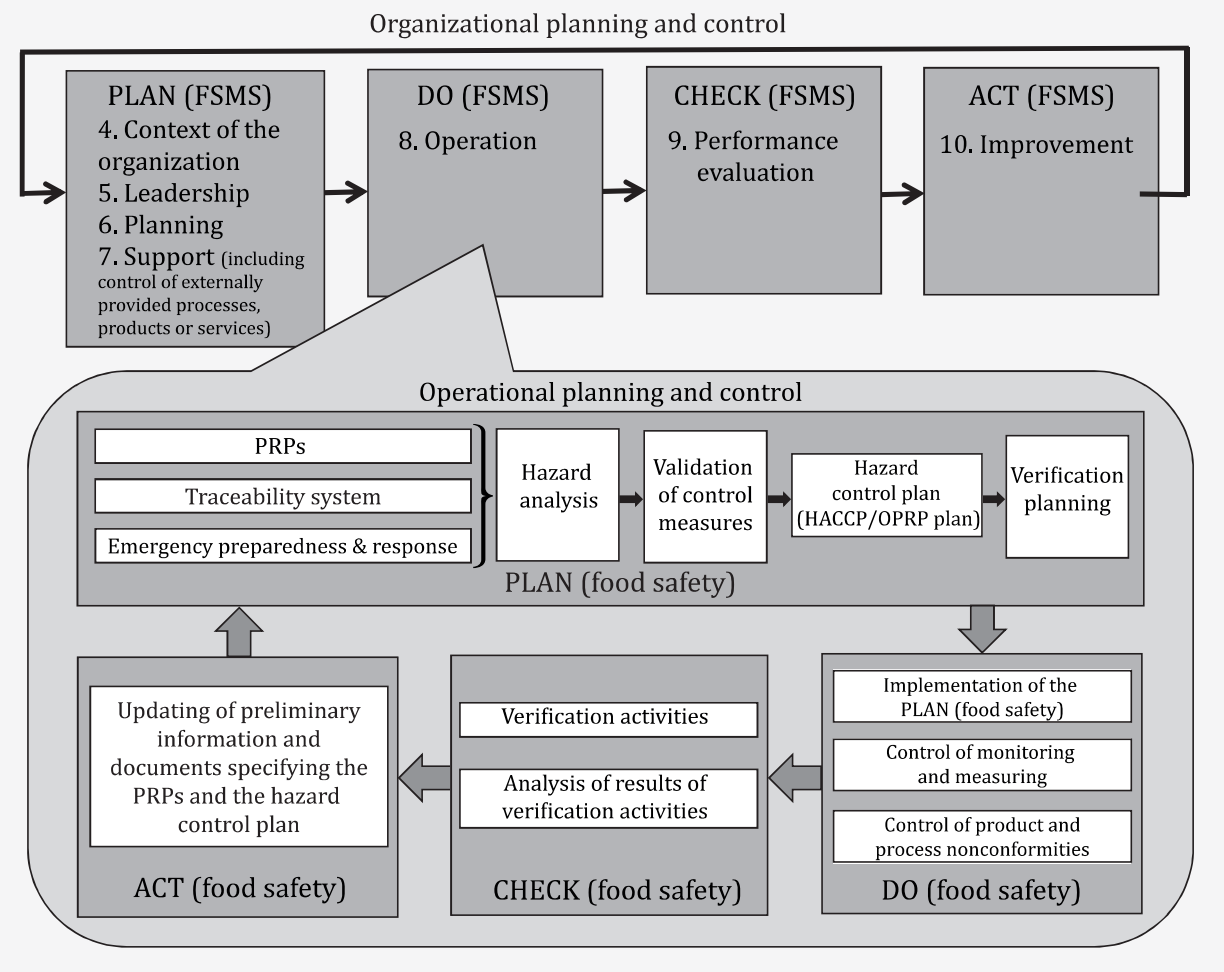


Figure 1 — Illustration of the Plan-Do-Check-Act cycle at the two levels

0.3.3 Risk-based thinking

0.3.3.1 General

Risk-based thinking is essential for achieving an effective FSMS. In this document, risk-based thinking is addressed on two levels, organizational (see 0.3.3.2) and operational (see 0.3.3.3), which is consistent with the process approach described in 0.3.2.

0.3.3.2 Organizational risk management

Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. In the context of organizational risk management, a positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

To conform to the requirements of this document, an organization plans and implements actions to address organizational risks (Clause 6). Addressing risks establishes a basis for increasing the effectiveness of the FSMS, achieving improved results and preventing negative effects.

0.3.3.3 Hazard analysis — Operational processes

The concept of risk-based thinking based on the HACCP principles at the operational level is implicit in this document.

The subsequent steps in HACCP can be considered as the necessary measures to prevent hazards or reduce hazards to acceptable levels to ensure food is safe at the time of consumption (Clause 8).

Decisions taken in the application of HACCP should be based on science, free from bias and documented. The documentation should include any key assumptions in the decision-making process.

0.4 Relationship with other management system standards

This document has been developed within the ISO high level structure (HLS). The objective of the HLS is to improve alignment between ISO management system standards. This document enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its FSMS approach with the requirements of other management systems and supporting standards.

This document is the core principle and framework for FSMSs and sets out the specific FSMS requirements for organizations throughout the food chain. Other guidance related to food safety, specifications and/or requirements specific to food sectors can be used together with this framework.

In addition, ISO has developed a family of associated documents. These include documents for:

— prerequisite programmes (ISO/TS 22002 series) for specific sectors of the food chain;

— requirements for auditing and certification bodies;

— traceability.

ISO also provides guidance documents for organizations on how to implement this document and related standards. Information is available on the ISO website.

Food safety management systems — Requirements for any organization in the food chain

1 Scope

This document specifies requirements for a food safety management system (FSMS) to enable an organization that is directly or indirectly involved in the food chain:

a) to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use;

b) to demonstrate compliance with applicable statutory and regulatory food safety requirements;

c) to evaluate and assess mutually agreed customer food safety requirements and to demonstrate conformity with them;

d) to effectively communicate food safety issues to interested parties within the food chain;

e) to ensure that the organization conforms to its stated food safety policy;

f) to demonstrate conformity to relevant interested parties;

g) to seek certification or registration of its FSMS by an external organization, or make a self-assessment or self-declaration of conformity to this document.

All requirements of this document are generic and are intended to be applicable to all organizations in the food chain, regardless of size and complexity. Organizations that are directly or indirectly involved include, but are not limited to, feed producers, animal food producers, harvesters of wild plants and animals, farmers, producers of ingredients, food manufacturers, retailers, and organizations providing food services, catering services, cleaning and sanitation services, transportation, storage and distribution services, suppliers of equipment, cleaning and disinfectants, packaging materials and other food contact materials.

This document allows any organization, including small and/or less developed organizations (e.g. a small farm, a small packer-distributor, a small retail or food service outlet) to implement externally-developed elements in their FSMS.

Internal and/or external resources can be used to meet the requirements of this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
acceptable level
level of a *food safety hazard* (3.22) not to be exceeded in the *end product* (3.15) provided by the *organization* (3.31)

3.2
action criterion
measurable or observable specification for the *monitoring* (3.27) of an *OPRP* (3.30)

Note 1 to entry: An action criterion is established to determine whether an OPRP remains in control, and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended).

3.3
audit
systematic, independent and documented *process* (3.36) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

Note 4 to entry: Relevant disciplines are, for example, food safety management, quality management or environmental management.

3.4
competence
ability to apply knowledge and skills to achieve intended results

3.5
conformity
fulfilment of a *requirement* (3.38)

3.6
contamination
introduction or occurrence of a contaminant including a *food safety hazard* (3.22) in a *product* (3.37) or processing environment

3.7
continual improvement
recurring activity to enhance *performance* (3.33)

3.8
control measure
action or activity that is essential to prevent a significant *food safety hazard* (3.22) or reduce it to an *acceptable level* (3.1)

Note 1 to entry: See also *significant food safety hazard* (3.40).

Note 2 to entry: Control measure(s) is (are) identified by hazard analysis.

3.9
correction
action to eliminate a detected *nonconformity* (3.28)

Note 1 to entry: A correction includes the handling of potentially unsafe products and can therefore be made in conjunction with a *corrective action* (3.10).

Note 2 to entry: A correction may be, for example, reprocessing, further processing and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

3.10
corrective action
action to eliminate the cause of a *nonconformity* (3.28) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action includes cause analysis.

3.11
critical control point
CCP
step in the *process* (3.36) at which *control measure(s)* (3.8) is (are) applied to prevent or reduce a *significant food safety hazard* (3.40) to an acceptable level, and defined *critical limit(s)* (3.12) and *measurement* (3.26) enable the application of *corrections* (3.9)

3.12
critical limit
measurable value which separates acceptability from unacceptability

Note 1 to entry: Critical limits are established to determine whether a *CCP* (3.11) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products.

[SOURCE: CAC/RCP 1-1969, modified — The definition has been modified and Note 1 to entry has been added.]

3.13
documented information
information required to be controlled and maintained by an *organization* (3.31) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:

— the management system (3.25), including related processes (3.36);

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

3.14
effectiveness
extent to which planned activities are realized and planned results achieved

3.15
end product
product (3.37) that will undergo no further processing or transformation by the *organization* (3.31)

Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

3.16
feed
single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to food-producing animals

Note 1 to entry: Distinctions are made in this document between the terms *food* (3.18), *feed* (3.16) and *animal food* (3.19):

— food is intended for consumption by humans and animals, and includes feed and animal food;

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

[SOURCE: CAC/GL 81-2013, modified — The word "materials" has been changed to "products" and "directly" has been deleted.]

3.17
flow diagram
schematic and systematic presentation of the sequence and interactions of steps in the process

3.18
food
substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances (ingredients) used only as drugs

Note 1 to entry: Distinctions are made in this document between the terms *food* (3.18), *feed* (3.16) and *animal food* (3.19):

— food is intended for consumption by humans and animals, and includes feed and animal food;

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

[SOURCE: CAC/GL 81-2013, modified — The word "human" has been deleted.]

3.19
animal food
single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to non-food-producing animals

Note 1 to entry: Distinctions are made in this document between the terms *food* (3.18), *feed* (3.16) and *animal food* (3.19):

— food is intended for consumption by humans and animals, and includes feed and animal food;

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

[SOURCE: CAC/GL 81-2013, modified — The word "materials" has been changed to "products", "non" has been added and "directly" has been deleted.]

3.20
food chain
sequence of the stages in the production, processing, distribution, storage and handling of a *food* (3.18) and its ingredients, from primary production to consumption

Note 1 to entry: This includes the production of *feed* (3.16) and *animal food* (3.19).

Note 2 to entry: The food chain also includes the production of materials intended to come into contact with food or raw materials.

Note 3 to entry: The food chain also includes service providers.

3.21
food safety
assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use

Note 1 to entry: Food safety is related to the occurrence of *food safety hazards* (3.22) in *end products* (3.15) and does not include other health aspects related to, for example, malnutrition.

Note 2 to entry: It is not to be confused with the availability of, and access to, food ("food security").

Note 3 to entry: This includes feed and animal food.

[SOURCE: CAC/RCP 1-1969, modified — The word "harm" has been changed to "adverse health effect" and notes to entry have been added.]

3.22
food safety hazard
biological, chemical or physical agent in *food* (3.18) with the potential to cause an adverse health effect

Note 1 to entry: The term "hazard" is not to be confused with the term "*risk*" (3.39) which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (e.g. death, hospitalization) when exposed to a specified hazard.

Note 2 to entry: Food safety hazards include allergens and radiological substances.

Note 3 to entry: In the context of feed and feed ingredients, relevant food safety hazards are those that can be present in and/or on feed and feed ingredients and that can through animal consumption of feed be transferred to food and can thus have the potential to cause an adverse health effect for the animal or the human consumer. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, disinfectants), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended (see 8.5.1.4).

Note 4 to entry: In the context of animal food, relevant food safety hazards are those that are hazardous to the animal species for which the food is intended.

[SOURCE: CAC/RCP 1-1969, modified — The phrase "or condition of" has been deleted from the definition and notes to entry have been added.]

3.23
interested party (preferred term)
stakeholder (admitted term)
person or *organization* (3.31) that can affect, be affected by, or perceive itself to be affected by a decision or activity

3.24
lot
defined quantity of a *product* (3.37) produced and/or processed and/or packaged essentially under the same conditions

Note 1 to entry: The lot is determined by parameters established beforehand by the organization and may be described by other terms, e.g. batch.

Note 2 to entry: The lot may be reduced to a single unit of product.

[SOURCE: CODEX STAN 1, modified — Reference to "and/or processed and/or packaged" has been included in the definition and notes to entry have been added.]

3.25
management system
set of interrelated or interacting elements of an *organization* (3.31) to establish *policies* (3.34) and *objectives* (3.29) and *processes* (3.36) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

Note 4 to entry: Relevant disciplines are, for example, a quality management system or an environmental management system.

3.26
measurement
process (3.36) to determine a value

3.27
monitoring
determining the status of a system, a *process* (3.36) or an activity

Note 1 to entry: To determine the status, there may be a need to check, supervise or critically observe.

Note 2 to entry: In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.

Note 3 to entry: Distinctions are made in this document between the terms *validation* (3.44), *monitoring* (3.27) and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of conformity.

3.28
nonconformity
non-fulfilment of a *requirement* (3.38)

3.29
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and *process* (3.36)).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a FSMS objective, or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of FSMS, objectives are set by the organization, consistent with the food safety policy, to achieve specific results.

3.30
operational prerequisite programme
OPRP
control measure (3.8) or combination of control measures applied to prevent or reduce a *significant food safety hazard* (3.40) to an *acceptable level* (3.1), and where *action criterion* (3.2) and *measurement* (3.26) or observation enable effective control of the *process* (3.36) and/or *product* (3.37)

3.31
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.29)

Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

3.32
outsource, verb
make an arrangement where an external *organization* (3.31) performs part of an organization's function or *process* (3.36)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.25), although the outsourced function or process is within the scope.

3.33
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.36), *products* (3.37) (including services), systems or *organizations* (3.31).

3.34
policy
intentions and direction of an *organization* (3.31) as formally expressed by its *top management* (3.41)

3.35
prerequisite programme
PRP
basic conditions and activities that are necessary within the *organization* (3.31) and throughout the *food chain* (3.20) to maintain food safety

Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are: good agricultural practice (GAP), good veterinary practice (GVP), good manufacturing practice (GMP), good hygiene practice (GHP), good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP).

3.36
process
set of interrelated or interacting activities which transforms inputs to outputs

3.37
product
output that is a result of a *process* (3.36)

Note 1 to entry: A product can be a service.

3.38
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in documented information.

3.39
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected – positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73:2009, 3.5.1.3) and "consequences" (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

Note 5 to entry: Food safety risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in *food* (3.18), as specified in the Codex Procedural Manual[11].

3.40
significant food safety hazard
food safety hazard (3.22), identified through the hazard assessment, which needs to be controlled by *control measures* (3.8)

3.41
top management
person or group of people who directs and controls an *organization* (3.31) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.25) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.42
traceability
ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

Note 1 to entry: Movement can relate to the origin of the materials, processing history or distribution of the *food* (3.18).

Note 2 to entry: An object can be a *product* (3.37), a material, a unit, equipment, a service, etc.

[SOURCE: CAC/GL 60-2006, modified — Notes to entry have been added.]

3.43
update
immediate and/or planned activity to ensure application of the most recent information

Note 1 to entry: Update is different from the terms "maintain" and "retain":

— "maintain" is to keep something on-going/to keep in good condition;

— "retain" is to keep something that is retrievable.

3.44
validation
<food safety> obtaining evidence that a *control measure* (3.8) (or combination of control measures) will be capable of effectively controlling the *significant food safety hazard* (3.40)

Note 1 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.

Note 2 to entry: Distinctions are made in this document between the terms *validation* (3.44), *monitoring* (3.27) and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of conformity.

3.45
verification
confirmation, through the provision of objective evidence, that specified *requirements* (3.38) have been fulfilled

Note 1 to entry: Distinctions are made in this document between the terms *validation* (3.44), *monitoring* (3.27) and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of conformity.

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its FSMS.

The organization shall identify, review and update information related to these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the context can be facilitated by considering external and internal issues, including, but not limited to, legal, technological, competitive, market, cultural, social and economic environments, cybersecurity and food fraud, food defence and intentional contamination, knowledge and performance of the organization, whether international, national, regional or local.

4.2 Understanding the needs and expectations of interested parties

To ensure that the organization has the ability to consistently provide products and services that meet applicable statutory, regulatory and customer requirements with regard to food safety, the organization shall determine:

a) the interested parties that are relevant to the FSMS;

b) the relevant requirements of the interested parties of the FSMS.

The organization shall identify, review and update information related to the interested parties and their requirements.

4.3 Determining the scope of the food safety management system

The organization shall determine the boundaries and applicability of the FSMS to establish its scope. The scope shall specify the products and services, processes and production site(s) that are included in the FSMS. The scope shall include the activities, processes, products or services that can have an influence on the food safety of its end products.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements referred to in 4.2.

The scope shall be available and maintained as documented information.

4.4 Food safety management system

The organization shall establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions, in accordance with the requirements of this document.

5 Leadership

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the FSMS by:

a) ensuring that the food safety policy and the objectives of the FSMS are established and are compatible with the strategic direction of the organization;

b) ensuring the integration of the FSMS requirements into the organization's business processes;

c) ensuring that the resources needed for the FSMS are available;

d) communicating the importance of effective food safety management and conforming to the FSMS requirements, applicable statutory and regulatory requirements, and mutually agreed customer requirements related to food safety;

e) ensuring that the FSMS is evaluated and maintained to achieve its intended result(s) (see 4.1);

f) directing and supporting persons to contribute to the effectiveness of the FSMS;

g) promoting continual improvement;

h) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this document can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 Policy

5.2.1 Establishing the food safety policy

Top management shall establish, implement and maintain a food safety policy that:

a) is appropriate to the purpose and context of the organization;

b) provides a framework for setting and reviewing the objectives of the FSMS;

c) includes a commitment to satisfy applicable food safety requirements, including statutory and regulatory requirements and mutually agreed customer requirements related to food safety;

d) addresses internal and external communication;

e) includes a commitment to continual improvement of the FSMS;

f) addresses the need to ensure competencies related to food safety.

5.2.2 Communicating the food safety policy

The food safety policy shall:

a) be available and maintained as documented information;

b) be communicated, understood and applied at all levels within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

5.3.1 Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the FSMS conforms to the requirements of this document;

b) reporting on the performance of the FSMS to top management;

c) appointing the food safety team and the food safety team leader;

d) designating persons with defined responsibility and authority to initiate and document action(s).

5.3.2 The food safety team leader shall be responsible for:

a) ensuring the FSMS is established, implemented, maintained and updated;

b) managing and organizing the work of the food safety team;

c) ensuring relevant training and competencies for the food safety team (see 7.2);

d) reporting to top management on the effectiveness and suitability of the FSMS.

5.3.3 All persons shall have the responsibility to report problem(s) with regards to the FSMS to identified person(s).

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the FSMS, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and 4.3 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the FSMS can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve continual improvement.

NOTE In the context of this document, the concept of risks and opportunities is limited to events and their consequences relating to the performance and effectiveness of the FSMS. Public authorities are responsible for addressing public health risks. Organizations are required to manage food safety hazards (see 3.22) and the requirements related to this process that are laid down in Clause 8.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its FSMS processes;

2) evaluate the effectiveness of these actions.

6.1.3 The actions taken by the organization to address risks and opportunities shall be proportionate to:

a) the impact on food safety requirements;

b) the conformity of food products and services to customers;

c) requirements of interested parties in the food chain.

NOTE 1 Actions to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or accepting the presence of risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices (modification of products or processes), using new technology and other desirable and viable possibilities to address the food safety needs of the organization or its customers.

6.2 Objectives of the food safety management system and planning to achieve them

6.2.1 The organization shall establish objectives for the FSMS at relevant functions and levels.

The objectives of the FSMS shall:

a) be consistent with the food safety policy;

b) be measurable (if practicable);

c) take into account applicable food safety requirements, including statutory, regulatory and customer requirements;

d) be monitored and verified;

e) be communicated;

f) be maintained and updated as appropriate.

The organization shall retain documented information on the objectives for the FSMS.

6.2.2 When planning how to achieve its objectives for the FSMS, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the FSMS, including personnel changes, the changes shall be carried out and communicated in a planned manner.

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the continued integrity of the FSMS;

c) the availability of resources to effectively implement the changes;

d) the allocation or re-allocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, update and continual improvement of the FSMS.

The organization shall consider:

a) the capability of, and any constraints on, existing internal resources;

b) the need for external resources.

7.1.2 People

The organization shall ensure that persons necessary to operate and maintain an effective FSMS are competent (see 7.2).

Where the assistance of external experts is used for the development, implementation, operation or assessment of the FSMS, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information.

7.1.3 Infrastructure

The organization shall provide the resources for the determination, establishment and maintenance of the infrastructure necessary to achieve conformity with the requirements of the FSMS.

NOTE Infrastructure can include:

— land, vessels, buildings and associated utilities;

— equipment, including hardware and software;

— transportation;

— information and communication technology.

7.1.4 Work environment

The organization shall determine, provide and maintain the resources for the establishment, management and maintenance of the work environment necessary to achieve conformity with the requirements of the FSMS.

NOTE A suitable environment can be a combination of human and physical factors such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, air flow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Externally developed elements of the food safety management system

When an organization establishes, maintains, updates and continually improves its FSMS by using externally developed elements of a FSMS, including PRPs, the hazard analysis and the hazard control plan (see 8.5.4), the organization shall ensure that the provided elements are:

a) developed in conformance with requirements of this document;

b) applicable to the sites, processes and products of the organization;

c) specifically adapted to the processes and products of the organization by the food safety team;

d) implemented, maintained and updated as required by this document;

e) retained as documented information.

7.1.6 Control of externally provided processes, products or services

The organization shall:

a) establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers of processes, products and/or services;

b) ensure adequate communication of requirements to the external provider(s);

c) ensure that externally provided processes, products or services do not adversely affect the organization's ability to consistently meet the requirements of the FSMS;

d) retain documented information of these activities and any necessary actions as a result of the evaluations and re-evaluations.

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s), including external providers, doing work under its control that affects its food safety performance and effectiveness of the FSMS;

b) ensure that these persons, including the food safety team and those responsible for the operation of the hazard control plan, are competent on the basis of appropriate education, training and/or experience;

c) ensure that the food safety team has a combination of multi-disciplinary knowledge and experience in developing and implementing the FSMS (including, but not limited to, the organization’s products, processes, equipment and food safety hazards within the scope of the FSMS);

d) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

e) retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

The organization shall ensure that all relevant persons doing work under the organization’s control shall be aware of:

a) the food safety policy;

b) the objectives of the FSMS relevant to their task(s);

c) their individual contribution to the effectiveness of the FSMS, including the benefits of improved food safety performance;

d) the implications of not conforming with the FSMS requirements.

7.4 Communication

7.4.1 General

The organization shall determine the internal and external communications relevant to the FSMS, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

The organization shall ensure that the requirement for effective communication is understood by all persons whose activities have an impact on food safety.

7.4.2 External communication

The organization shall ensure that sufficient information is communicated externally and is available for interested parties of the food chain.

The organization shall establish, implement and maintain effective communications with:

a) external providers and contractors;

b) customers and/or consumers, in relation to:

   1) product information related to food safety, to enable the handling, display, storage, preparation, distribution and use of the product within the food chain or by the consumer;

   2) identified foods safety hazards that need to be controlled by other organizations in the food chain and/or by consumers;

   3) contractual arrangements, enquiries and orders, including their amendments;

   4) customer and/or consumer feedback, including complaints;

c) statutory and regulatory authorities;

d) other organizations that have an impact on, or will be affected by, the effectiveness or updating of the FSMS.

Designated persons shall have defined responsibility and authority for the external communication of any information concerning food safety. Where relevant, information obtained through external communication shall be included as input for management review (see 9.3) and for updating the FSMS (see 4.4 and 10.3).

Evidence of external communication shall be retained as documented information.

7.4.3 Internal communication

The organization shall establish, implement and maintain an effective system for communicating issues having an impact on food safety.

To maintain the effectiveness of the FSMS, the organization shall ensure that the food safety team is informed in a timely manner of changes in the following:

a) products or new products;

b) raw materials, ingredients and services;

c) production systems and equipment;

d) production premises, location of equipment and surrounding environment;

e) cleaning and sanitation programmes;

f) packaging, storage and distribution systems;

g) competencies and/or allocation of responsibilities and authorizations;

h) applicable statutory and regulatory requirements;

i) knowledge regarding food safety hazards and control measures;

j) customer, sector and other requirements that the organization observes;

k) relevant enquiries and communications from external interested parties;

l) complaints and alerts indicating food safety hazards associated with the end product;

m) other conditions that have an impact on food safety.

The food safety team shall ensure that this information is included when updating the FSMS (see 4.4 and 10.3).

Top management shall ensure that relevant information is included as input to the management review (see 9.3).

7.5 Documented information

7.5.1 General

The organization's FSMS shall include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the FSMS;

c) documented information and food safety requirements required by statutory, regulatory authorities and customers.

NOTE The extent of documented information for a FSMS can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the FSMS and by this document shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the FSMS shall be identified, as appropriate, and controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products, and to implement the actions determined in 6.1, by:

a) establishing criteria for the processes;

b) implementing control of the processes in accordance with the criteria;

c) keeping documented information to the extent necessary to have the confidence to demonstrate that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 7.1.6).

8.2 Prerequisite programmes (PRPs)

8.2.1 The organization shall establish, implement, maintain and update PRP(s) to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment.

8.2.2 The PRP(s) shall be:

a) appropriate to the organization and its context with regard to food safety;

b) appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled;

c) implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or process;

d) approved by the food safety team.

8.2.3 When selecting and/or establishing PRP(s), the organization shall ensure that applicable statutory, regulatory and mutually agreed customer requirements are identified. The organization should consider:

a) the applicable part of the ISO/TS 22002 series;

b) applicable standards, codes of practice and guidelines.

8.2.4 When establishing PRP(s) the organization shall consider:

a) construction, lay-out of buildings and associated utilities;

b) lay-out of premises, including zoning, workspace and employee facilities;

c) supplies of air, water, energy and other utilities;

d) pest control, waste and sewage disposal and supporting services;

e) the suitability of equipment and its accessibility for cleaning and maintenance;

f) supplier approval and assurance processes (e.g. raw materials, ingredients, chemicals and packaging);

g) reception of incoming materials, storage, dispatch, transportation and handling of products;

h) measures for the prevention of cross contamination;

i) cleaning and disinfecting;

j) personal hygiene;

k) product information/consumer awareness;

l) others, as appropriate.

Documented information shall specify the selection, establishment, applicable monitoring and verification of the PRP(s).

8.3 Traceability system

The traceability system shall be able to uniquely identify incoming material from the suppliers and the first stage of the distribution route of the end product. When establishing and implementing the traceability system, the following shall be considered as a minimum:

a) relation of lots of received materials, ingredients and intermediate products to the end products;

b) reworking of materials/products;

c) distribution of the end product.

The organization shall ensure that applicable statutory, regulatory and customer requirements are identified.

Documented information as evidence of the traceability system shall be retained for a defined period to include, as a minimum, the shelf life of the product. The organization shall verify and test the effectiveness of the traceability system.

NOTE Where appropriate, the verification of the system is expected to include the reconciliation of quantities of end products with the quantity of ingredients as evidence of effectiveness.

8.4 Emergency preparedness and response

8.4.1 General

Top management shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety which are relevant to the role of the organization in the food chain.

Documented information shall be established and maintained to manage these situations and incidents.

8.4.2 Handling of emergencies and incidents

The organization shall:

a) respond to actual emergency situations and incidents by:

   1) ensuring applicable statutory and regulatory requirements are identified;

   2) communicating internally;

   3) communicating externally (e.g. suppliers, customers, appropriate authorities, media);

b) take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident and the potential food safety impact;

c) periodically test procedures where practical;

d) review and, where necessary, update the documented information after the occurrence of any incident, emergency situation or tests.

NOTE Examples of emergency situations that can affect food safety and/or production are natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents, e.g. interruption of essential services such as water, electricity or refrigeration supply.

8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.1 General

To carry out the hazard analysis, preliminary documented information shall be collected, maintained and updated by the food safety team. This shall include, but not be limited to:

a) applicable statutory, regulatory and customer requirements;

b) the organization's products, processes and equipment;

c) food safety hazards relevant to the FSMS.

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials

The organization shall ensure that all applicable statutory and regulatory food safety requirements are identified for all raw materials, ingredients and product contact materials.

The organization shall maintain documented information concerning all raw materials, ingredients and product contact materials to the extent needed to conduct the hazard analysis (see 8.5.2), including the following, as appropriate:

a) biological, chemical and physical characteristics;

b) composition of formulated ingredients, including additives and processing aids;

c) source (e.g. animal, mineral or vegetable);

d) place of origin (provenance);

e) method of production;

f) method of packaging and delivery;

g) storage conditions and shelf life;

h) preparation and/or handling before use or processing;

i) acceptance criteria related to food safety or specifications of purchased materials and ingredients appropriate to their intended use.

8.5.1.3 Characteristics of end products

The organization shall ensure that all applicable statutory and regulatory food safety requirements are identified for all the end products intended to be produced.

The organization shall maintain documented information concerning the characteristics of end products to the extent needed to conduct the hazard analysis (see 8.5.2), including information on the following, as appropriate:

a) product name or similar identification;

b) composition;

c) biological, chemical and physical characteristics relevant for food safety;

d) intended shelf life and storage conditions;

e) packaging;

f) labelling relating to food safety and/or instructions for handling, preparation and intended use;

g) method(s) of distribution and delivery.

8.5.1.4 Intended use

The intended use, including reasonably expected handling of the end product and any unintended use but reasonably expected mishandling and misuse of the end product, shall be considered and shall be maintained as documented information to the extent needed to conduct the hazard analysis (see 8.5.2).

Where appropriate, groups of consumers/users shall be identified for each product.

Groups of consumers/users known to be especially vulnerable to specific food safety hazards shall be identified.

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.1 Preparation of the flow diagrams

The food safety team shall establish, maintain and update flow diagrams as documented information for the products or product categories and the processes covered by the FSMS.

Flow diagrams provide a graphic representation of the process. Flow diagrams shall be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams shall, as appropriate, include the following:

a) the sequence and interaction of the steps in the operation;

b) any outsourced processes;

c) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;

d) where reworking and recycling take place;

e) where end products, intermediate products, by-products and waste are released or removed.

8.5.1.5.2 On-site confirmation of flow diagrams

The food safety team shall confirm on-site the accuracy of the flow diagrams, update the flow diagrams where appropriate and retain as documented information.

8.5.1.5.3 Description of processes and process environment

The food safety team shall describe, to the extent needed to conduct the hazard analysis:

a) the layout of premises, including food and non-food handling areas;

b) processing equipment and contact materials, processing aids and flow of materials;

c) existing PRPs, process parameters, control measures (if any) and/or the strictness with which they are applied, or procedures that can influence food safety;

d) external requirements (e.g. from statutory and regulatory authorities or customers) that can impact the choice and the strictness of the control measures.

The variations resulting from expected seasonal changes or shift patterns shall be included as appropriate.

The descriptions shall be updated as appropriate and maintained as documented information.

8.5.2 Hazard analysis

8.5.2.1 General

The food safety team shall conduct a hazard analysis, based on the preliminary information, to determine the hazards that need to be controlled. The degree of control shall ensure food safety and, where appropriate, a combination of control measures shall be used.

8.5.2.2 Hazard identification and determination of acceptable levels

8.5.2.2.1 The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment.

The identification shall be based on:

a) the preliminary information and data collected in accordance with 8.5.1;

b) experience;

c) internal and external information including, to the extent possible, epidemiological, scientific and other historical data;

d) information from the food chain on food safety hazards related to the safety of the end products, intermediate products and the food at the time of consumption;

e) statutory, regulatory and customer requirements.

NOTE 1 Experience can include information from staff and external experts who are familiar with the product and/or processes in other facilities.

NOTE 2 Statutory and regulatory requirements can include food safety objectives (FSOs). The Codex Alimentarius Commission defines FSOs as "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)".

Hazards should be considered in sufficient detail to enable hazard assessment and the selection of appropriate control measures.

8.5.2.2.2 The organization shall identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist.

When identifying hazards, the organization shall consider:

a) the stages preceding and following in the food chain;

b) all steps in the flow diagram;

c) the process equipment, utilities/services, process environment and persons.

8.5.2.2.3 The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible.

When determining acceptable levels, the organization shall:

a) ensure that applicable statutory, regulatory and customer requirements are identified;

b) consider the intended use of end products;

c) consider any other relevant information.

The organization shall maintain documented information concerning the determination of acceptable levels and the justification for the acceptable levels.

8.5.2.3 Hazard assessment

The organization shall conduct, for each identified food safety hazard, a hazard assessment to determine whether its prevention or reduction to an acceptable level is essential.

The organization shall evaluate each food safety hazard with regard to:

a) the likelihood of its occurrence in the end product prior to application of control measures;

b) the severity of its adverse health effects in relation to the intended use (see 8.5.1.4).

The organization shall identify any significant food safety hazards.

The methodology used shall be described, and the result of the hazard assessment shall be maintained as documented information.

8.5.2.4 Selection and categorization of control measure(s)

8.5.2.4.1 Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazards to defined acceptable levels.

The organization shall categorize the selected identified control measure(s) to be managed as OPRP(s) (see 3.30) or at CCPs (see 3.11).

The categorization shall be carried out using a systematic approach. For each of the control measures selected, there shall be an assessment of the following:

a) the likelihood of failure of its functioning;

b) the severity of the consequence in the case of failure of its functioning; this assessment shall include:

   1) the effect on identified significant food safety hazards;

   2) the location in relation to other control measure(s);

   3) whether it is specifically established and applied to reduce the hazards to an acceptable level;

   4) whether it is a single measure or is part of combination of control measure(s).

8.5.2.4.2 In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of:

a) establishing measurable critical limits and/or measurable/observable action criteria;

b) monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;

c) applying timely corrections in case of failure.

The decision-making process and results of the selection and categorization of the control measures shall be maintained as documented information.

External requirements (e.g. statutory, regulatory and customer requirements) that can impact the choice and the strictness of the control measures shall also be maintained as documented information.

8.5.3 Validation of control measure(s) and combinations of control measures

The food safety team shall validate that the selected control measures are capable of achieving the intended control of the significant food safety hazard(s). This validation shall be done prior to implementation of control measure(s) and combinations of control measures to be included in the hazard control plan (see 8.5.4) and after any change therein (see 7.4.2, 7.4.3, 10.2 and 10.3).

When the result of validation shows that the control measures(s) is (are) not capable of achieving the intended control, the food safety team shall modify and re-assess the control measure(s) and/or combination(s) of control measure(s).

The food safety team shall maintain the validation methodology and evidence of capability of the control measure(s) to achieve the intended control as documented information.

NOTE Modification can include changes in control measure(s) (i.e. process parameters, rigour and/or their combination) and/or change(s) in the manufacturing technologies for raw materials, end product characteristics, methods of distribution and intended use of the end products.

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.1 General

The organization shall establish, implement and maintain a hazard control plan. The hazard control plan shall be maintained as documented information and shall include the following information for each control measure at each CCP or OPRP:

a) food safety hazard(s) to be controlled at the CCP or by the OPRP;

b) critical limit(s) at CCP or action criteria for OPRP;

c) monitoring procedure(s);

d) correction(s) to be made if critical limits or action criteria are not met;

e) responsibilities and authorities;

f) records of monitoring.

8.5.4.2 Determination of critical limits and action criteria

Critical limits at CCPs and action criteria for OPRPs shall be specified. The rationale for their determination shall be maintained as documented information.

Critical limits at CCPs shall be measurable. Conformance with critical limits shall ensure that the acceptable level is not exceeded.

Action criteria for OPRPs shall be measurable or observable. Conformance with action criteria shall contribute to the assurance that the acceptable level is not exceeded.

8.5.4.3 Monitoring systems at CCPs and for OPRPs

At each CCP, a monitoring system shall be established for each control measure or combination of control measure(s) to detect any failure to remain within the critical limits. The system shall include all scheduled measurements relative to the critical limit(s).

For each OPRP, a monitoring system shall be established for the control measure or combination of control measure(s) to detect failure to meet the action criterion.

The monitoring system, at each CCP and for each OPRP, shall consist of documented information, including:

a) measurements or observations that provide results within an adequate time frame;

b) monitoring methods or devices used;

c) applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations (see 8.7);

d) monitoring frequency;

e) monitoring results;

f) responsibility and authority related to monitoring;

g) responsibility and authority related to evaluation of monitoring results.

At each CCP, the monitoring method and frequency shall be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product (see 8.9.4).

For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.

When monitoring an OPRP is based on subjective data from observations (e.g. visual inspection), the method shall be supported by instructions or specifications.

8.5.4.4 Actions when critical limits or action criteria are not met

The organization shall specify corrections (see 8.9.2) and corrective actions (see 8.9.3) to be taken when critical limits or action criterion are not met and shall ensure that:

a) the potentially unsafe products are not released (see 8.9.4);

b) the cause of nonconformity is identified;

c) the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria;

d) recurrence is prevented.

The organization shall make corrections in accordance with 8.9.2 and corrective actions in accordance with 8.9.3.

8.5.4.5 Implementation of the hazard control plan

The organization shall implement and maintain the hazard control plan, and retain evidence of the implementation as documented information.

8.6 Updating the information specifying the PRPs and the hazard control plan

Following the establishment of the hazard control plan, the organization shall update the following information, if necessary:

a) characteristics of raw materials, ingredients and product-contact materials;

b) characteristics of end products;

c) intended use;

d) flow diagrams and descriptions of processes and process environment.

The organization shall ensure that the hazard control plan and/or the PRP(s) are up to date.

8.7 Control of monitoring and measuring

The organization shall provide evidence that the specified monitoring and measuring methods and equipment in use are adequate for the monitoring and measuring activities related to the PRP(s) and the hazard control plan.

The monitoring and measuring equipment used shall be:

a) calibrated or verified at specified intervals prior to use;

b) adjusted or re-adjusted as necessary;

c) identified to enable the calibration status to be determined;

d) safeguarded from adjustments that would invalidate the measurement results;

e) protected from damage and deterioration.

The results of calibration and verification shall be retained as documented information. The calibration of all the equipment shall be traceable to international or national measurement standards; where no standards exist, the basis used for calibration or verification shall be retained as documented information.

The organization shall assess the validity of the previous measurement results when the equipment or process environment is found not to conform to requirements. The organization shall take appropriate action in relation to the equipment or process environment and any product affected by the non-conformance.

The assessment and resulting action shall be maintained as documented information.

Software used in monitoring and measuring within the FSMS shall be validated by the organization, software supplier or third party prior to use. Documented information on validation activities shall be maintained by the organization and the software shall be updated in a timely manner.

Whenever there are changes, including software configuration/modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

8.8 Verification related to PRPs and the hazard control plan

8.8.1 Verification

The organization shall establish, implement and maintain verification activities. The verification planning shall define purpose, methods, frequencies and responsibilities for the verification activities.

The verification activities shall confirm that:

a) the PRP(s) are implemented and effective;

b) the hazard control plan is implemented and effective;

c) hazard levels are within identified acceptable levels;

d) input to the hazard analysis is updated;

e) other actions determined by the organization are implemented and effective.

The organization shall ensure that verification activities are not carried out by the person responsible for monitoring the same activities.

Verification results shall be retained as documented information and shall be communicated.

Where verification is based on testing of end product samples or direct process samples and where such test samples show nonconformity with the acceptable level of the food safety hazard (see 8.5.2.2), the organization shall handle the affected lot(s) of product as potentially unsafe (see 8.9.4.3) and apply corrective actions in accordance with 8.9.3.

8.8.2 Analysis of results of verification activities

The food safety team shall conduct an analysis of the results of verification that shall be used as an input to the performance evaluation of the FSMS (see 9.1.2).

8.9 Control of product and process nonconformities

8.9.1 General

The organization shall ensure that data derived from the monitoring of OPRPs and at CCPs are evaluated by designated persons who are competent and have the authority to initiate corrections and corrective actions.

8.9.2 Corrections

8.9.2.1 The organization shall ensure that when critical limits at CCP(s) and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release.

The organization shall establish, maintain and update documented information that includes:

a) a method of identification, assessment and correction for affected products to ensure their proper handling;

b) arrangements for review of the corrections carried out.

8.9.2.2 When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (see 8.9.4).

8.9.2.3 Where action criteria for an OPRP are not met, the following shall be carried out:

a) determination of the consequences of that failure with respect to food safety;

b) determination of the cause(s) of failure;

c) identification of the affected products and handling in accordance with 8.9.4.

The organization shall retain results of the evaluation as documented information.

8.9.2.4 Documented information shall be retained to describe corrections made on nonconforming products and processes, including:

a) the nature of the nonconformity;

b) the cause(s) of the failure;

c) the consequences as a result of the nonconformity.

8.9.3 Corrective actions

The need for corrective actions shall be evaluated when critical limits at CCP(s) and/or action criteria for OPRPs are not met.

The organization shall establish and maintain documented information that specifies appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to return the process to control after a nonconformity is identified.

These actions shall include:

a) reviewing nonconformities identified by customer and/or consumer complaints and/or regulatory inspection reports;

b) reviewing trends in monitoring results that can indicate loss of control;

c) determining the cause(s) of nonconformities;

d) determining and implementing actions to ensure that nonconformities do not recur;

e) documenting the results of corrective actions taken;

f) verifying corrective actions taken to ensure that they are effective.

The organization shall retain documented information on all corrective actions.

8.9.4 Handling of potentially unsafe products

8.9.4.1 General

The organization shall take action(s) to prevent potentially unsafe products from entering the food chain, unless it can demonstrate that:

a) the food safety hazard(s) of concern is (are) reduced to the defined acceptable levels;

b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the food chain; or

c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

The organization shall retain products that have been identified as potentially unsafe under its control until the products have been evaluated and the disposition has been determined.

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal/recall (see 8.9.5).

The controls and related responses from relevant interested parties and authorization for dealing with potentially unsafe products shall be retained as documented information.

8.9.4.2 Evaluation for release

Each lot of products affected by the nonconformity shall be evaluated.

Products affected by failure to remain within critical limits at CCPs shall not be released, but shall be handled in accordance with 8.9.4.3.

Products affected by failure to meet action criterion for OPRPs shall only be released as safe when any of the following conditions apply:

a) evidence other than the monitoring system demonstrates that the control measures have been effective;

b) evidence shows that the combined effect of the control measures for that particular product conforms to the performance intended (i.e. identified acceptable levels);

c) the results of sampling, analysis and/or other verification activities demonstrate that the affected products conform to the identified acceptable levels for the food safety hazard(s) concerned.

Results of evaluation for release of products shall be retained as documented information.

8.9.4.3 Disposition of nonconforming products

Products that are not acceptable for release shall be:

a) reprocessed or further processed within or outside the organization to ensure that the food safety hazard is reduced to acceptable levels; or

b) redirected for other use as long as food safety in the food chain is not affected; or

c) destroyed and/or disposed as waste.

Documented information on the disposition of nonconforming products, including the identification of the person(s) with approving authority shall be retained.

8.9.5 Withdrawal/recall

The organization shall be able to ensure the timely withdrawal/recall of lots of end products that have been identified as potentially unsafe, by appointing competent person(s) having the authority to initiate and carry out the withdrawal/recall.

The organization shall establish and maintain documented information for:

a) notifying relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers);

b) handling withdrawn/recalled products as well as products still in stock;

c) performing the sequence of actions to be taken.

Withdrawn/recalled products and end products still in stock shall be secured or held under the control of the organization until they are managed in accordance with 8.9.4.3.

The cause, extent and result of a withdrawal/recall shall be retained as documented information and reported to the top management as input for the management review (see 9.3).

The organization shall verify the implementation and effectiveness of withdrawals/recalls through the use of appropriate techniques (e.g. mock withdrawal/recall or practice withdrawal/recall) and retain documented information.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated;

e) who shall analyse and evaluate the results from monitoring and measurement.

The organization shall retain appropriate documented information as evidence of the results.

The organization shall evaluate the performance and the effectiveness of the FSMS.

9.1.2 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement, including the results of verification activities related to PRPs and the hazard control plan (see 8.8 and 8.5.4), the internal audits (see 9.2) and external audits.

The analysis shall be carried out:

a) to confirm that the overall performance of the system meets the planned arrangements and the FSMS requirements established by the organization;

b) to identify the need for updating or improving the FSMS;

c) to identify trends which indicate a higher incidence of potentially unsafe products or process failures;

d) to establish information for planning of the internal audit programme related to the status and importance of areas to be audited;

e) to provide evidence that corrections and corrective actions are effective.

The results of the analysis and the resulting activities shall be retained as documented information. The results shall be reported to top management and used as input to the management review (see 9.3) and the updating of the FSMS (see 10.3).

NOTE Methods to analyse data can include statistical techniques.

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the FSMS:

a) conforms to:

   1) the organization's own requirements for its FSMS;

   2) the requirements of this document;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain (an) audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes in the FSMS, and the results of monitoring, measurement and previous audits;

b) define the audit criteria and scope for each audit;

c) select competent auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to the food safety team and relevant management;

e) retain documented information as evidence of the implementation of the audit programme and the audit results;

f) make the necessary correction and take the necessary corrective action within the agreed time frame;

g) determine if the FSMS meets the intent of the food safety policy (see 5.2) and objectives of the FSMS (see 6.2).

Follow-up activities by the organization shall include the verification of the actions taken and the reporting of the verification results.

NOTE ISO 19011 provides guidelines for auditing management systems.

9.3 Management review

9.3.1 General

Top management shall review the organization's FSMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

9.3.2 Management review input

The management review shall consider:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the FSMS, including changes in the organization and its context (see 4.1);

c) information on the performance and the effectiveness of the FSMS, including trends in:

   1) result(s) of system updating activities (see 4.4 and 10.3);

   2) monitoring and measurement results;

   3) analysis of the results of verification activities related to PRPs and the hazard control plan (see 8.8.2);

   4) nonconformities and corrective actions;

   5) audit results (internal and external);

   6) inspections (e.g. regulatory, customer);

   7) the performance of external providers;

   8) the review of risks and opportunities and of the effectiveness of actions taken to address them (see 6.1);

   9) the extent to which objectives of the FSMS have been met;

d) the adequacy of resources;

e) any emergency situation, incident (see 8.4.2) or withdrawal/recall (see 8.9.5) that occurred;

f) relevant information obtained through external (see 7.4.2) and internal (see 7.4.3) communication, including requests and complaints from interested parties;

g) opportunities for continual improvement.

The data shall be presented in a manner that enables top management to relate the information to stated objectives of the FSMS.

9.3.3 Management review output

The outputs of the management review shall include:

a) decisions and actions related to continual improvement opportunities;

b) any need for updates and changes to the FSMS, including resource needs and revision of the food safety policy and objectives of the FSMS.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 Nonconformity and corrective action

10.1.1 When a nonconformity occurs, the organization shall:

a) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the FSMS, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.1.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.2 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the FSMS.

Top management shall ensure that the organization continually improves the effectiveness of the FSMS through the use of communication (see 7.4), management review (see 9.3), internal audit (see 9.2), analysis of results of verification activities (see 8.8.2), validation of control measure(s) and combination(s) of control measure(s) (see 8.5.3), corrective actions (see 8.9.3) and FSMS updating (see 10.3).

10.3 Update of the food safety management system

Top management shall ensure that the FSMS is continually updated. To achieve this, the food safety team shall evaluate the FSMS at planned intervals. The team shall consider whether it is necessary to review the hazard analysis (see 8.5.2), the established hazard control plan (see 8.5.4) and the established PRPs (see 8.2). The updating activities shall be based on:

a) input from communication, external as well as internal (see 7.4);

b) input from other information concerning the suitability, adequacy and effectiveness of the FSMS;

c) output from the analysis of results of verification activities (see 9.1.2);

d) output from management review (see 9.3).

System updating activities shall be retained as documented information and reported as input to the management review (see 9.3).

Annex A
(informative)

Cross references between the CODEX HACCP and this document

Table A.1 — Cross references between the CODEX HACCP principles and application steps and clauses of this document

CODEX HACCP Principles	CODEX HACCP application steps[a]		This document	
	Assemble HACCP team	Step 1	5.3	Food safety team
	Describe product	Step 2	8.5.1.2 8.5.1.3	Characteristics of raw materials, ingredients and product-contact materials Characteristics of end products
	Identify intended use	Step 3	8.5.1.4	Intended use
	Construct flow diagram On-site confirmation of flow diagram	Step 4 Step 5	8.5.1.5	Flow diagrams and descriptions of processes
Principle 1 Conduct a hazard analysis	List all potential hazards Conduct a hazard analysis Consider control measures	Step 6	8.5.2 8.5.3	Hazard analysis Validation of control measure(s) and combinations of control measure(s)
Principle 2 Determine the critical control points (CCPs)	Determine CCPs	Step 7	8.5.4	Hazard control plan
Principle 3 Establish critical limit(s)	Establish critical limits for each CCP	Step 8	8.5.4	Hazard control plan
Principle 4 Establish a system to monitor control of the CCP	Establish a monitoring system for each CCP	Step 9	8.5.4.3	Monitoring systems at CCPs and for OPRPs
Principle 5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control	Establish corrective actions	Step 10	8.5.4 8.9.2 8.9.3	Hazard control plan Corrections Corrective actions
Principle 6 Establish procedures for verification to confirm that the HACCP system is working effectively	Establish verification procedures	Step 11	8.7 8.8 9.2	Control of monitoring and measuring Verification related to PRPs and the hazard control plan Internal audit
Principle 7 Establish documentation concerning all procedures and records appropriate to these principles and their application	Establish documentation and record keeping	Step 12	7.5	Documented information

[a] CODEX publications are available via Reference [12].

Annex B
(informative)

Cross references between this document and ISO 22000:2005

Table B.1 — Main structure

This document	ISO 22000:2005
4 Context of the organization	New heading
4.1 Understanding the organization and its context	New
4.2 Understanding the needs and expectations of interested parties	New
4.3 Determining the scope of the food safety management system	4.1 (and new)
4.4. Food safety management system	4.1
5 Leadership	New heading
5.1 Leadership and commitment	5.1, 7.4.3 (and new)
5.2 Policy	5.2 (and new)
5.3 Organizational roles, responsibilities and authorities	5.4, 5.5, 7.3.2 (and new)
6 Planning	New heading
6.1 Actions to address risks and opportunities	New
6.2 Objectives of the food safety management system and planning to achieve them	5.3 (and new)
6.3 Planning of changes	5.3 (and new)
7 Support	New heading
7.1 Resources	1, 4.1, 6.2, 6.3, 6.4 (and new)
7.2 Competence	6.2, 7.3.2 (and new)
7.3 Awareness	6.2.2
7.4 Communication	5.6, 6.2.2
7.5 Documented information	4.2, 5.6.1
8 Operation	New heading
8.1 Operational planning and control	New
8.2 Prerequisite programmes (PRPs)	7.2
8.3 Traceability system	7.9 (and new)
8.4 Emergency preparedness and response	5.7 (and new)
8.5 Hazard control	7.3, 7.4, 7.5, 7.6, 8.2 (and new)
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	7.8, 8.4.2
8.9 Control of product and process nonconformities	7.10
9 Performance evaluation	New heading
9.1 Monitoring, measurement, analysis and evaluation	New heading
9.1.1 General	New
9.1.2 Analysis and evaluation	8.4.2, 8.4.3
9.2 Internal audit	8.4.1
9.3 Management review	5.8 (and new)
9.3.1 General	5.2, 5.8.1

Table B.1 *(continued)*

This document	ISO 22000:2005
9.3.2 Management review input	5.8.2 (and new)
9.3.3 Management review output	5.8.1, 5.8.3
10 Improvement	New heading
10.1 Nonconformity and corrective action	New
10.2 Continual improvement	8.1, 8.5.1
10.3 Update of the food safety management system	8.5.2

Table B.2 — Clause 7: Support

This document	ISO 22000:2005
7 Support	New heading
7.1. Resources	6
7.1.1 General	6.1
7.1.2 People	6.2, 6.2.2 (and new)
7.1.3 Infrastructure	6.3
7.1.4 Work environment	6.4
7.1.5 Externally developed elements of the food safety management system	1 (and new)
7.1.6 Control of externally provided processes, products or services	4.1 (and new)
7.2 Competence	6.2.1, 6.2.2, 7.3.2
7.3 Awareness	6.2.2
7.4 Communication	5.6
7.4.1 General	6.2.2 (and new)
7.4.2 External communication	5.6.1
7.4.3 Internal communication	5.6.2
7.5 Documented information	4.2
7.5.1 General	4.2.1, 5.6.1
7.5.2 Creating and updating	4.2.2
7.5.3 Control of documented information	4.2.2, 4.2.3 (and new)

Table B.3 — Clause 8: Operation

This document	ISO 22000:2005
8 Operation	New heading
8.1 Operational planning and control	7.1 (and new)
8.2 Prerequisite programmes (PRPs)	7.2
8.3 Traceability system	7.9 (and new)
8.4 Emergency preparedness and response	5.7
8.4.1 General	5.7
8.4.2 Handling of emergencies and incidents	New
8.5 Hazard control	New heading
8.5.1 Preliminary steps to enable hazard analysis	7.3
8.5.1.1 General	7.3.1
8.5.1.2 Characteristics of raw materials, ingredients and product contact materials	7.3.3.1
8.5.1.3 Characteristics of end products	7.3.3.2
8.5.1.4 Intended use	7.3.4

Table B.3 *(continued)*

This document	ISO 22000:2005
8.5.1.5 Flow diagrams and description of processes	7.3.5.1
8.5.1.5.1 Preparation of flow diagrams	7.3.5.1
8.5.1.5.2 On-site confirmation of flow diagrams	7.3.5.1
8.5.1.5.3 Description of processes and process environment	7.2.4, 7.3.5.2 (and new)
8.5.2 Hazard analysis	7.4
8.5.2.1 General	7.4.1
8.5.2.2 Hazard identification and determination of acceptable levels	7.4.2
8.5.2.3 Hazard assessment	7.4.3, 7.6.2 (and new)
8.5.2.4 Selection and categorization of control measure(s)	7.3.5.2, 7.4.4 (and new)
8.5.3 Validation of control measure(s) and combination(s) of control measure(s)	8.2
8.5.4 Hazard control plan (HACCP/OPRP plan)	New heading
8.5.4.1 General	7.5, 7.6.1
8.5.4.2 Determination of critical limits and action criteria	7.6.3 (and new)
8.5.4.3 Monitoring systems at CCPs and for OPRPs	7.6.3, 7.6.4 (and new)
8.5.4.4 Actions when critical limits or action criteria are not met	7.6.5
8.5.4.5 Implementation of the hazard control plan	New
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	New heading
8.8.1 Verification	7.8, 8.4.2
8.8.2 Analysis of results of verification activities	8.4.3
8.9 Control of product and process nonconformities	7.10
8.9.1 General	7.10.1, 7.10.2
8.9.2 Corrections	7.10.1
8.9.3 Corrective actions	7.10.2
8.9.4 Handling of potentially unsafe products	7.10.3
8.9.4.1 General	7.10.3.1
8.9.4.2 Evaluation for release	7.10.3.2
8.9.4.3 Disposition of nonconforming products	7.10.3.3
8.9.5 Withdrawal/recall	7.10.4

Bibliography

[1] ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

[2] ISO 9001:2015, *Quality management systems — Requirements*

[3] ISO 19011, *Guidelines for auditing management systems*

[4] ISO/TS 22002 (all parts), *Prerequisite programmes on food safety*

[5] ISO/TS 22003, *Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems*

[6] ISO 22005, *Traceability in the feed and food chain — General principles and basic requirements for system design and implementation*

[7] ISO Guide 73:2009, *Risk management — Vocabulary*

[8] CAC/GL 60-2006, *Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System*

[9] CAC/GL 81-2013, *Guidance for governments on prioritizing hazards in feed*

[10] CAC/RCP 1-1969, *General Principles of Food Hygiene*

[11] Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission: Procedural Manual. Twenty-fifth edition, 2016

[12] Codex Alimentarius. Available from: http://www.fao.org/fao-who-codexalimentarius/en/

ICS 67.020; 03.100.70

Price based on 37 pages

GAP Unit
Bangladesh Agricultural Research Council
Farmgate, Dhaka-1215, Bangladesh
www.barc.gov.bd