8.6.2 Notice of changes by a certification body

The certification body shall give its certified clients due notice of any changes to its requirements for certification. The certification body shall verify that each certified client complies with the new requirements.

NOTE Contractual arrangements with certified clients could 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 found in Annex E of ISO/IEC Guide 28:2004.

8.6.3 Notice of changes by a client

The certification body shall have legally enforceable arrangements to ensure that the certified client informs the certification body, without delay, of matters that may affect the capability of the management system to continue to fulfil the requirements of the standard used for certification. These include, for example, changes relating to

a) the legal, commercial, organizational status or ownership,

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

c) contact address and sites,

d) scope of operations under the certified management system, and

e) major changes to the management system and processes.

NOTE A model of license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is found in Annex E of ISO/IEC Guide 28:2004.

9 Process requirements

9.1 General requirements

9.1.1 The certification body shall precisely define the scope of certification in terms of levels of the food chain (e.g. primary production, food processing, packaging material production), category(ies) and sectors according to Annex A.

The certification body shall not exclude part of the processes, sectors, products or services from the scope of certification when those processes, sectors, products or services have an influence on the food safety of the end products.

9.1.2 The certification body shall have a process for choosing the audit day, time and season so that the audit team has the opportunity of auditing the organization operating on a representative number of product lines, categories and sectors covered by the scope.

9.1.3 All the requirements given in 9.1.1 to 9.1.3 of ISO/IEC 17021:2006 apply.

9.1.4 The certification body shall have documented procedures for determining audit time, and for each client the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's FSMS.

The audit time determined by the certification body, and the justification for the determination, shall be recorded. In determining the audit time, the certification body should consider Annex B and shall consider, among other things, the following aspects:

a) requirements of the relevant FSMS standard;
b) size and complexity of the organization;
c) technological and regulatory context;
d) any outsourcing of any activities included in the scope of the FSMS;
e) results of any prior audits;
f) number of sites and multi-site considerations.

9.1.5 For multi-site organizations, the requirements given in 9.1.5.1 and 9.5.1.3 apply.

9.1.5.1 Where the certification body is certifying a multi-site organization under one certificate, the following conditions apply:

a) all sites are of the same activity and are located within the same country;
b) all sites are operating under one centrally controlled and administered FSMS as defined in Clause 4 of ISO 22000:2005, or equivalent for other FSMSs;
c) an internal audit has been conducted on each site within the three years prior to certification;
d) following certification, an internal audit shall be carried out on each site within the certification period;
e) the internal audits of all sites shall comply with ISO 22000 or equivalent;
f) audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

9.1.5.2 The use of multi-site sampling is only possible for organizations with more than 20 sites and only for categories A, B, G, H and J (see Table A.1).

This applies both to the initial certification and to surveillance audits.

9.1.5.3 Where the certification body offers multi-site certification, the certification body shall utilize a sampling programme to ensure an effective audit of the FSMS where

a) the sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites with a minimum of 20. All sites shall be randomly selected and, after the audit, no sampled sites may be nonconforming (i.e. not meeting certification thresholds for ISO 22000),
b) evaluation of the audit findings of the sampled sites shall be deemed equivalent to the internal audit findings of the same sites of the organization,
c) at least annually, an audit of the central FSMS shall be performed,
d) at least annually, surveillance audits shall be performed on the sampled sites, and
e) audit findings of the sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

Table 1 gives examples of the number of sites to audit when sampling is used.

Table 1 — Examples of the number of sites to be audited when multi-site sampling is used

Table 1 — Examples of the number of sites to be audited when multi-site sampling is used

	Total number of sites								
	x between 1 and 20	21	22	23	24	25	26	27	28
Number of sites above 20	0	1	2	3	4	5	6	7	8
Additional number of sites to audit	0	1	1	1	1	1	2	2	2
Number of sites to be audited	x	21	21	21	21	21	22	22	22

9.1.6 All the requirements given in 9.1.6 to 9.1.9 of ISO/IEC 17021:2006 apply.

9.1.7 The certification body shall provide a written report for each audit. The report shall be based on relevant guidance provided in ISO 19011.

The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the certification body.

The report shall include references to PRPs used by the organization, HACCP methodology used, comments on the HACCP team, and other issues relevant to the FSMS.

9.1.8 All the requirements given in 9.1.11 to 9.1.15 of ISO/IEC 17021:2006 apply.

9.2 Initial audit and certification

9.2.1 Application

All the requirements given in 9.2.1 of ISO/IEC 17021:2006 apply. The certification body shall require the applicant organization to provide detailed information concerning process lines, HACCP studies and the number of shifts.

9.2.2 Application review

All the requirements given in 9.2.2 of ISO/IEC 17021:2006 apply.

9.2.3 Initial certification audit

The initial certification audit of an FSMS shall be conducted in two stages: stage 1 and stage 2.

9.2.3.1 Stage 1 audits

9.2.3.1.1 All the requirements given in 9.2.3.1.1 of ISO/IEC 17021:2006 apply.

Where an organization has implemented an externally developed combination of control measures, the stage 1 audit shall review the documentation included in the FSMS to determine if the combination of control measures is suitable for the organization, was developed in compliance with the requirements of ISO 22000, and is kept up to date.

The availability of relevant authorizations should be checked when collecting the information regarding the compliance to regulatory aspects.

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

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

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

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

d) the FSMS is designed to achieve the organization's food safety policy,

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

f) the validation, verification and improvement programmes conform to the requirements of the FSMS standard,

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

h) additional documentation needs to be reviewed and/or what knowledge needs to be obtained in advance.

9.2.3.1.3 For FSMS, the stage 1 audit shall be carried out at the client's premises in order to achieve the objectives stated above.

9.2.3.1.4 All the requirements given in 9.2.3.1.2 of ISO/IEC 17021:2006 apply.

The client shall be informed that the results of the stage 1 audit may lead to postponement or cancellation of the stage 2 audit.

9.2.3.1.5 Any part of the FSMS that is audited during the stage 1 audit and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit.

However, the certification body shall ensure that the already audited parts of the FSMS continue to conform to the certification requirements. In this case, the stage 2 audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

9.2.3.1.6 All the requirements given in 9.2.3.1.3 of ISO/IEC 17021:2006 apply. The interval between stage 1 and stage 2 audits is reasonably expected to be not longer than 6 months.

The stage 1 audit should be repeated if a longer interval is needed.

9.2.3.2 Stage 2 audit

All the requirements given in 9.2.3.2 of ISO/IEC 17021:2006 apply.

9.2.3.2 Stage 2 audit

The purpose of the stage 2 audit is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 audit shall take place at the site(s) of the client. It shall include at least the following:

a) information and evidence about conformity to all requirements of the applicable management system standard or other normative document;

b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document);

c) the client's management system and performance as regards legal compliance;

d) operational control of the client's processes;

e) internal auditing and management review;

f) management responsibility for the client's policies;

g) links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions.

9.2.4 Initial certification audit conclusions

All the requirements given in 9.2.4 of ISO/IEC 17021:2006 apply.

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9.2.4 Initial certification audit conclusions

The audit team shall analyse all information and audit evidence gathered during the stage 1 and stage 2 audits to review the audit findings and agree on the audit conclusions.

9.2.5 Information for granting initial certification

All the requirements given in 9.2.5 of ISO/IEC 17021:2006 apply.

9.2.5 Information for granting initial certification

9.2.5.1 The information provided by the audit team to the certification body for the certification decision shall include, as a minimum,

a) the audit reports,

b) comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client,

c) confirmation of the information provided to the certification body used in the application review (see 9.2.2), and

d) a recommendation whether or not to grant certification, together with any conditions or observations.

9.2.5.2 The certification body shall make the certification decision on the basis of an evaluation of the audit findings and conclusions and any other relevant information (e.g. public information, comments on the audit report from the client).

9.3 Surveillance activities

All the requirements given in 9.3 of ISO/IEC 17021:2006 apply.

9.3 Surveillance activities

9.3.1 General

9.3.1.1 The certification body shall develop its surveillance activities so that representative areas and functions covered by the scope of the management system are monitored on a regular basis, and take into account changes to its certified client and its management system.

9.3.1.2 Surveillance activities shall include on-site audits assessing the certified client's management system's fulfilment of specified requirements with respect to the standard to which the certification is granted. Other surveillance activities may include

a) enquiries from the certification body to the certified client on aspects of certification,

b) reviewing any client's statements with respect to its operations (e.g. promotional material, website),

c) requests to the client to provide documents and records (on paper or electronic media), and

d) other means of monitoring the certified client's performance.

9.3 Surveillance activities

All the requirements given in 9.3 of ISO/IEC 17021:2006 apply.

9.3.2 Surveillance audit

9.3.2.1 Surveillance audits are on-site audits, but are not necessarily full system audits, and shall be planned together with the other surveillance activities so that the certification body can maintain confidence that the certified management system continues to fulfil requirements between recertification audits. The surveillance audit programme shall include, at least

a) internal audits and management review,

b) a review of actions taken on nonconformities identified during the previous audit,

c) treatment of complaints,

d) effectiveness of the management system with regard to achieving the certified client's objectives,

e) progress of planned activities aimed at continual improvement,

f) continuing operational control,

g) review of any changes, and

h) use of marks and/or any other reference to certification.

9.3.2.2 Surveillance audits shall be conducted at least once a year. The date of the first surveillance audit following initial certification shall not be more than 12 months from the last day of the stage 2 audit.

9.3 Surveillance activities

All the requirements given in 9.3 of ISO/IEC 17021:2006 apply.

9.3.3 Maintaining certification

The certification body shall maintain certification based on demonstration that the client continues to satisfy the requirements of the management system standard. It may maintain a client's certification based on a positive conclusion by the audit team leader without further independent review, provided that

a) for any nonconformity or other situation that may lead to suspension or withdrawal of certification, the certification body has a system that requires the audit team leader to report to the certification body the need to initiate a review by appropriately competent personnel (see 7.2.9), different from those who carried out the audit, to determine whether certification can be maintained, and

b) competent personnel of the certification body monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

9.4 Recertification

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9.4 Recertification

All the requirements given in 9.4 of ISO/IEC 17021:2006 apply.

9.4 Recertification

9.4.1 Recertification audit planning

9.4.1.1 A recertification audit shall be planned and conducted to evaluate the continued fulfilment of all of the requirements of the relevant management system standard or other normative document. The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification.

9.4.1.2 The recertification audit shall consider the performance of the management system over the period of certification, and include the review of previous surveillance audit reports.

9.4.1.3 Recertification audit activities may need to have a stage 1 audit in situations where there have been significant changes to the management system, the client, or the context in which the management system is operating (e.g. changes to legislation).

9.4.1.4 In the case of multiple sites or certification to multiple management system standards being provided by the certification body, the planning for the audit shall ensure adequate on-site audit coverage to provide confidence in the certification.

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9.4 Recertification

All the requirements given in 9.4 of ISO/IEC 17021:2006 apply.

9.4.2 Recertification audit

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

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

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

c) whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives.

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

9.4.3 Information for granting recertification

The certification body shall make decisions on renewing certification based on the results of the recertification audit, as well as the results of the review of the system over the period of certification and complaints received from users of certification.

9.5 Special audits

All the requirements given in 9.5 of ISO/IEC 17021:2006 apply.

9.5 Special audits

9.5.1 Extensions to scope

The certification body shall, in response to an application for extension to the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with a surveillance audit.

9.5.2 Short-notice audits

It may be necessary for the certification body to conduct audits of certified clients at short notice to investigate complaints (see 9.8), or in response to changes (see 8.6.3), or as follow up on suspended clients (see 9.6). In such cases

a) the certification body shall describe and make known in advance to the certified clients (e.g. in documents as described in 8.6.1) the conditions under which these short notice visits are to be conducted, and

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

9.6 Suspending, withdrawing or reducing the scope of certification

All the requirements given in 9.6 of ISO/IEC 17021:2006 apply.

9.6 Suspending, withdrawing or reducing the scope of certification

9.6.1 The certification body shall have a policy and documented procedure(s) for suspension, withdrawal or reduction of the scope of certification, and shall specify the subsequent actions by the certification body.

9.6.2 The certification body shall suspend certification in cases when, for example,

— the client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system,

— the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies, or

— the certified client has voluntarily requested a suspension.

9.6.3 Under suspension, the client's management system certification is temporarily invalid. The certification body shall have enforceable arrangements with its clients to ensure that in case of suspension the client refrains from further promotion of its certification. The certification body shall make the suspended status of the certification publicly accessible (see 8.1.3) and shall take any other measures it deems appropriate.

9.6.4 Failure to resolve the issues that have resulted in the suspension in a time established by the certification body shall result in withdrawal or reduction of the scope of certification.

NOTE In most cases the suspension would not exceed 6 months.

9.6.5 The certification body shall reduce the client's scope of certification to exclude the parts not meeting the requirements, when the client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification. Any such reduction shall be in line with the requirements of the standard used for certification.

9.6.6 The certification body shall have enforceable arrangements with the certified client concerning conditions of withdrawal [see 8.4.3.d)] ensuring upon notice of withdrawal of certification that the client discontinues its use of all advertising matter that contains any reference to a certified status.

9.6.7 Upon request by any party, the certification body shall correctly state the status of certification of a client's management system as being suspended, withdrawn or reduced.

9.7 Appeals

All the requirements given in 9.7 of ISO/IEC 17021:2006 apply.

9.7 Appeals

9.7.1 The certification body shall have a documented process to receive, evaluate and make decisions on appeals.

9.7.2 A description of the appeals-handling process shall be publicly accessible.

9.7.3 The certification body shall be responsible for all decisions at all levels of the appeals-handling process. The certification body shall ensure that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions.

9.7.4 Submission, investigation and decision on appeals shall not result in any discriminatory actions against the appellant.

9.7.5 The appeals-handling process shall include at least the following elements and methods:

a) an outline of the process for receiving, validating and investigating the appeal, and for deciding what actions are to be taken in response to it, taking into account the results of previous similar appeals;

b) tracking and recording appeals, including actions undertaken to resolve them;

c) ensuring that any appropriate correction and corrective action are taken.

9.7.6 The certification body shall acknowledge receipt of the appeal and shall provide the appellant with progress reports and the outcome.

9.7.7 The decision to be communicated to the appellant shall be made by, or reviewed and approved by, individual(s) not previously involved in the subject of the appeal.

9.7.8 The certification body shall give formal notice to the appellant of the end of the appeals-handling process.

9.8 Complaints

All the requirements given in 9.8 of ISO/IEC 17021:2006 apply.

9.8 Complaints

9.8.1 A description of the complaints-handling process shall be publicly accessible.

9.8.2 Upon receipt of a complaint, the certification body shall confirm whether the complaint relates to certification activities that it is responsible for and, if so, shall deal with it. If the complaint relates to a certified client, then examination of the complaint shall consider the effectiveness of the certified management system.

9.8.3 Any complaint about a certified client shall also be referred by the certification body to the certified client in question at an appropriate time.

9.8.4 The certification body shall have a documented process to receive, evaluate and make decisions on complaints. This process shall be subject to requirements for confidentiality, as it relates to the complainant and to the subject of the complaint.

9.8.5 The complaints-handling process shall include at least the following elements and methods:

a) an outline of the process for receiving, validating, investigating the complaint, and for deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken in response to them;

c) ensuring that any appropriate correction and corrective action are taken.

NOTE ISO 10002 provides guidance for complaints handling.

9.8 Complaints

All the requirements given in 9.8 of ISO/IEC 17021:2006 apply.

9.8.6 The certification body receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

9.8.7 Whenever possible, the certification body shall acknowledge receipt of the complaint, and shall provide the complainant with progress reports and the outcome.

9.8.8 The decision to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not previously involved in the subject of the complaint.

9.8.9 Whenever possible, the certification body shall give formal notice of the end of the complaints-handling process to the complainant.

9.8.10 The certification body shall determine, together with the client and the complainant, whether and, if so to what extent, the subject of the complaint and its resolution shall be made public.

9.9 Records of applicants and clients

All the requirements given in 9.9 of ISO/IEC 17021:2006 apply.

9.9 Records of applicants and clients

9.9.1 The certification body shall maintain records on the audit and other certification activities for all clients, including all organizations that submitted applications, and all organizations audited, certified, or with certification suspended or withdrawn.

9.9.2 Records on certified clients shall include the following:

a) application information and initial, surveillance and recertification audit reports;

b) certification agreement;

c) justification of the methodology used for sampling;

d) justification for auditor time determination (see 9.1.4);

e) verification of correction and corrective actions;

f) records of complaints and appeals, and any subsequent correction or corrective actions;

g) committee deliberations and decisions, if applicable;

9.9 Records of applicants and clients

All the requirements given in 9.9 of ISO/IEC 17021:2006 apply.

h) documentation of the certification decisions;

i) certification documents, including the scope of certification with respect to product, process or service, as applicable;

j) related records necessary to establish the credibility of the certification, such as evidence of the competence of auditors and technical experts.

NOTE Methodology of sampling includes the sampling employed to assess the specific management system and/or to select sites in the context of multi-site assessment.

9.9 Records of applicants and clients

All the requirements given in 9.9 of ISO/IEC 17021:2006 apply.

h) documentation of the certification decisions;

i) certification documents, including the scope of certification with respect to product, process or service, as applicable;

j) related records necessary to establish the credibility of the certification, such as evidence of the competence of auditors and technical experts.

NOTE Methodology of sampling includes the sampling employed to assess the specific management system and/or to select sites in the context of multi-site assessment.

9.9.3 The certification body shall keep the records on applicants and clients secure to ensure that the information is kept confidential. Records shall be transported, transmitted or transferred in a way that ensures that confidentiality is maintained.

9.9.4 The certification body shall have a documented policy and documented procedures on the retention of records. Records shall be retained for the duration of the current cycle plus one full certification cycle.

NOTE In some jurisdictions, the law stipulates that records need to be maintained for a longer time period.

10 Management system requirements for certification bodies
All the requirements given in Clause 10 of ISO/IEC 17021:2006 apply.

10 Management system requirements for certification bodies

10.1 Options

The certification body shall establish and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard. In addition to meeting the requirements of Clauses 5 to 9, the certification body shall implement a management system in accordance with either

a) management system requirements in accordance with ISO 9001 (see 10.2), or

b) general management system requirements (see 10.3).

10.2 Option 1: Management system requirements in accordance with ISO 9001

10.2.1 General

The certification body shall establish and maintain a management system, in accordance with the requirements of ISO 9001, that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard, amplified by 10.2.2 to 10.2.5.

10.2.2 Scope

For application of the requirements of ISO 9001, the scope of the management system shall include the design and development requirements for its certification services.

10.2.3 Customer focus

For application of the requirements of ISO 9001, when developing its management system, the certification body shall consider the credibility of certification and shall address the needs of all parties (as set out in 4.1.2) that rely upon its audit and certification services, not just its clients.

10.2.4 Management review

For application of the requirements of ISO 9001, the certification body shall include as input for management review, information on relevant appeals and complaints from users of certification activities.

10.2.5 Design and development

For application of the requirements of ISO 9001, when developing a new management system certification scheme, or adapting an existing one to special circumstances, the certification body shall ensure that the guidance given in ISO 19011, and which is appropriate to third-party situations, is included as a design input.

10.3 Option 2: General management system requirements

10.3.1 General

The certification body shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International Standard.

The certification body's top management shall establish and document policies and objectives for its activities. The top management shall provide evidence of its commitment to the development and implementation of the management system in accordance with the requirements of this International Standard. The top management shall ensure that the policies are understood, implemented and maintained at all levels of the certification body's organization.

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

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

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

10.3.2 Management system manual

All applicable requirements of this International Standard shall be addressed either in a manual or in associated documents. The certification body shall ensure that the manual and relevant associated documents are accessible to all relevant personnel.

10.3.3 Control of documents

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

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

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

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

e) to ensure that documents remain legible and readily identifiable,

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

g) to 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.

10.3.4 Control of records

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.

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

NOTE For requirements for records on certified clients, see also 9.9.

10.3.5 Management review

10.3.5.1 General

The certification body's top management shall establish procedures to review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard. These reviews shall be conducted at least once a year.

10.3.5.2 Review inputs

The input to the management review shall include information related to

a) results of internal and external audits,

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

c) feedback from the committee 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, and

h) appeals and complaints.

10.3.5.3 Review outputs

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

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

b) improvement of the certification services related to the fulfilment of this International Standard, and

c) resource needs.

10.3.6 Internal audits

10.3.6.1 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.

10.3.6.2 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.

10.3.6.3 Internal audits shall be performed at least once every 12 months. The frequency of internal audits may be reduced if the certification body can demonstrate that its management system continues to be effectively implemented according to this International Standard and has proven stability.

10.3.6.4 The certification body shall ensure that

a) internal audits are conducted by qualified 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, and

e) any opportunities for improvement are identified.

10.3.7 Corrective actions

The certification body shall establish procedures for identification and management of nonconformities in its operations. The certification body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the impact of the problems encountered. The procedures shall define requirements for

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 in a timely manner, the actions needed,

f) recording the results of actions taken, and

g) reviewing the effectiveness of corrective actions.

10.3.8 Preventive actions

The certification body shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities. Preventive actions taken shall be appropriate to the probable impact of the potential problems. The procedures for preventive actions shall define requirements for

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, and

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 (normative)

Classification of food chain categories

The certification body shall use Table A.1

a)to define the scope that it undertakes,

b) to identify if any technical qualification of its auditors is necessary for that particular category or sector, and

c) to select a suitably qualified audit team.

The examples given in Table A.1 are not exhaustive but are only an indication of relevant topics.

The scope of one specific client organization may cover more than one category.

Table A.1 — Food chain categories

Category codes	Categories	Examples of sectors
A	Farming 1 (Animals)	animals; fish; egg production; milk production; beekeeping; fishing; hunting; trapping
B	Farming 2 (Plants)	fruits; vegetables; grain; spices; horticultural products
C	Processing 1 (Perishable animal products) including all activities after farming, e.g. slaughtering	meat, poultry, eggs, dairy and fish products
D	Processing 2 (Perishable vegetal products)	fresh fruits and fresh juices; preserved fruits; fresh vegetables; preserved vegetables
E	Processing 3 (Products with long shelf life at ambient temperature)	canned products; biscuits; snacks; oil; drinking water; beverages; pasta; flour; sugar; salt
F	Feed production	animal feed; fish feed
G	Catering	hotels; restaurants
H	Distribution	retail outlets; shops; wholesalers
I	Services	water supply; cleaning; sewage; waste disposal; development of product, process and equipment; veterinary services
J	Transport and storage	transport and storage
K	Equipment manufacturing	process equipment; vending machines
L	(Bio)chemical manufacturing	additives; vitamins; pesticides; drugs; fertilizers; cleaning agents; biocultures
M	Packaging material manufacturing	packaging material

Minimum audit time

B.1 General

In determining the audit time needed for each site, as required in 9.1.4, the certification body should consider the minimum on-site duration for initial certification given in Table B.1.

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

The minimum audit time is established for the audit of an FSMS which includes only one HACCP study. A HACCP study corresponds to a hazard analysis for a family of products/services with similar hazards and similar production technology and, where relevant, similar storage technology.

The minimum surveillance audit time should be one-third of the initial certification audit time, with a minimum of 0,5 audit days. The minimum renewal time should be two-thirds of the initial certification audit time, with a minimum of 0,5 audit days.

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

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The number of employees should be expressed as the number of full-time equivalent employees (FTEs).

Certain categories are subject to multi-site sampling (see 9.1.5.2) and this may be taken into account when calculating the audit time.

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

B.2 Calculation of minimum initial certification audit time

B.2.1 Minimum audit time for single site, Ts:

$$Ts = (D + H + MS + FTE)$$

where

D is the basis on-site audit time;

H is the audit days for additional HACCP studies;

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

FTE is the audit days per number of employees.

B.2.2 Minimum audit time for each additional site, Tm:

$$Tm = Ts \times 50/100$$

Table B.1 — Minimum initial certification audit time

Category (see Annex A)	D Basic on-site audit time (in audit days)	H For each additional HACCP study (in audit days)	MS Absence of certified relevant management system (in audit days)	FTE Number of employees (in audit days)	For each additional site visited
A	0,75	0,25	0,25	1 to 19 = 0 20 to 49 = 0,5 50 to 79 = 1,0 80 to 199 = 1,5 200 to 499 = 2,0 500 to 899 = 2,5 900 to 1 299 = 3,0 1 300 to 1 699 = 3,5 1 700 to 2 999 = 4,0 3 000 to 5 000 = 4,5 > 5 000 = 5,0	50 % of minimum on-site audit time
B	0,75	0,25			
C	1,50	0,50			
D	1,00	0,50			
E	1,50	0,50			
F	1,50	0,50			
G	1,00	0,50			
H	1,00	0,50			
I	1,00	0,25			
J	1,00	0,25			
K	1,00	0,25			
L	1,50	0,50			
M	1,00	0,25			

END OF TRAINING

ON

ISO/TS 22003