MOLDAC REPUBLICA MOLDOVA	**NATIONAL CENTER OF ACCREDITATION**

GUIDANCE DOCUMENT FOR ACCREDITATION OF FOOD SAFETY MANAGEMENT SYSTEM CERTIFICATION BODIES

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CONTENT
Chapter name:

1. SCOPE

The purpose of this document is to describe the requirements for the accreditation of Food Safety Management Systems Certification Bodies according to SM SR EN ISO\IEC 17021-1:2015 and SM ISO\TS 22003:2004 and to EA, IAF, MOLDAC documents applicable to these standards in order to ensure a unified and consequent application.

2. PURPOSE

This document is applied by the entire MOLDAC personnel involved in the accreditation process of CABs, as well as by all stakeholders.

3. REFERENCE DOCUMENTS

- Law no. 235 of 01.12.2011 on accreditation and conformity assessment activities with subsequent amendments
- SM SR EN ISO/IEC 17000:2006 Conformity assessment. Vocabulary and general principles
- SM SR EN ISO/IEC 17011:2017 Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies.
- SM SR EN ISO/IEC 17021-1:2015 Conformity assessment. Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements.
- SM ISO/TS 22003:2014 Food safety management systems -- Requirements for bodies providing audit and certification of food safety management systems

EA and IAF documents applicable by the CB_{FSMS}:

IAF MD 1:2018	mandatory	IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization
IAF MD 2:2017	mandatory	IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
IAF MD 11:2019	mandatory (with application from 17.01.2021)	IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems
IAF ID 11:2015	informative	Information on the Transition of Management System Accreditation to ISO/IEC 17021-1:2015 from ISO/IEC 17021:2011

This is an informative document which provides guidelines regarding the transition of ISO/IEC 17021:2011 to ISO/IEC 17021-1:2015. Food safety management systems certification bodies must comply with the provisions of this document.

IAF MD 15:2014	mandatory	Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance

EA and IAF documents applicable by MOLDAC:

IAF MD 7:2010	mandatory	Harmonozation of Sanctions

This document is mandatory for the consistent application of clause 7.13 of ISO/IEC 17011 under specific conditions described herein. This document does not supersede any of the requirements of this standard. The provisions of this document are found in the accreditation contract.

IAF MD 10:2013	mandatory	IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011

The purpose of this document is to provide a harmonized approach on how the accreditation bodies assess the competence management of the certification bodies in accordance with ISO / IEC 17021: 2011.

IAF MD 12:2016	mandatory	Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries

This document is mandatory for the consistent application of Clause 7 of ISO/IEC 17011 on accreditation of Conformity Assessment Bodies (CABs) by NAB, when the CAB grants certifications outside the boarders of the country where is located the headquarter of CAB. Clauses 7.5.7 and 7.5.8 of ISO/IEC 17011 provide requirements for the assessment by NAB of sites where are performed key activities.

IAF MD 15:2014	mandatory	Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance

This document is mandatory from 14.07.2016 for the consistent application of Clause 7.11.2 of ISO/IEC 17011. All requirements of ISO / IEC 17011 continue to be applied and this document does not supersede any of the requirements of this standard. This mandatory document is exclusively for accreditation of management systems certification bodies.

IAF MD 16:2015	mandatory	Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

This document is mandatory for the consistent application of ISO/IEC 17011 in the accreditation process of Food Safety Management Systems Certification Bodies (CB_{FSMS}). All the requirements of ISO/IEC 17011 continue to be applied and this document does not supersede any requirement of the standard. The document aims to help the NAB to harmonize the application process of ISO/IEC 17011 for the accreditation of CB_{FSMS}. This document defines the activities that the NAB shall undertake to evaluate the competence of a CAB in each category of food chain defined in Annex A of ISO/TS 22003.

The rules and procedures of the National Accreditation Body

4. DEFINITIONS AND ABBREVIATIONS

4.1 Definitions

For the purposes of this document, apply the terms and definitions from the following standards:
- SM SR EN ISO/IEC 17000:2006 Conformity assessment. Vocabulary and general principles

- SM SR EN ISO/IEC 17011:2017 Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies

- SM SR EN ISO 9000:2016 - Quality management systems. Fundamentals and vocabulary

4.2 Abbreviations

NAB – National Accreditation Body
CAB – Conformity Assessment Body
CB – Certification Body
MS – Management System
QMS – Quality Management System
EMS – Environmental Management System
FSMS – Food Safety Management System
PCP – Product Certification Body
CB_{QMS} – Quality Management System Certification Body
CB_{FSMS} – Food Safety Management System Certification Body
CB_{EMS} – Environmental Management System Certification Body
CB_{ISMS} – Information Security Management System Certification Body
CB_{OSMS} – Occupational Safety Management System Certification Body
ND – Normative Document

5. DESCRIPTION OF REQUIREMENTS

The item numbers in this chapter correspond to the number of clauses from SM SR EN ISO/IEC 17021-1:2015 and SM ISO/TS 22003:2014.

5. General requirements 5.1 Legal and contractual matters

CB shall submit documents proving that it is a legal entity that has a legal agreement for the certification activities in accordance with the relevant requirements of this standard and that it is responsible for decisions on certification.

If the CB appeals to a committee which recommends the certification decision, the decision shall be taken after receiving the notification of this committee. The CB decision may be other than the positive notification of the Committee, in cases where it is found that the stipulated procedures were not respected or exist other serious and justified reasons (e.g: the applicant's insolvency etc.).

5.2 Impartiality Management

Conformity assessment activities shall be undertaken impartially. The CB shall be responsible for the impartiality of its conformity assessment activities and shall not allow commercial, financial or other pressures to compromise impartiality.
The CB shall have top management commitment to impartiality in management system certification activities and a policy public accessible that demonstrates that it understands the importance of impartiality manages conflict of interest and ensures the objectivity of its certification activities.
The CB shall have a process to identify, analyse, evaluate, treat, monitor, and document the risks related to conflict of interests arising from provision of certification including any conflicts arising from its relationships on an ongoing basis.

Where there are any threats to impartiality, the certification body shall document and demonstrate how it eliminates or minimizes such threats and document any residual risk. Top management shall review any residual risk to determine if it is within the level of acceptable risk.

The risk assessment process shall include identification of and consultation with appropriate interested parties to advice on matters affecting impartiality including openness and public perception.

The CB shall not:
- Certify the QMS of other CB;
- Offer or provide consultancy for FSMS;
- Perform internal audits for certified clients;
- Outsource audits to an consulting organization for FSMS;
- Present or offer that has interferences with the activities of a MS consultancy organization.

An acceptable reduction of this threat is that CB shall not:
- Certify an FSMS for which conducted internal audits;
- Offer or provide consultancy for FSMS;
- Conduct internal audits for certified clients;
- Involve personnel (including those involved in committees) who provided consultancy for FSMS, or participated in internal audits, or was employed within the applicant enterprise;
- Outsource audits to a management system consultancy organization for FSMS, for a period of minimum two years after their completion.

The certification body shall take action to respond to any threats to its impartiality arising from the actions of other persons, bodies or organizations.

All certification body personnel, either internal or external, or committees, who could influence the certification activities, shall act impartially and shall not allow commercial, financial or other pressures to compromise impartiality.
Certification bodies shall require personnel, to reveal any situation known to them that can present them or CB with a conflict of interests.

5.3 Liability and financing

The CB shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements to cover liabilities arising from its operations, in each of its fields of activities and the geographic areas in which it operates.
The CB shall evaluate its finances and sources of income and demonstrate that on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

6 Structural requirements

6.1 Organizational structure and top management

The CB shall document its organizational structure, duties, responsibilities and authorities of management and other personnel involved in certification and any committees.
Certification activities shall be structured and managed so as to safeguard impartiality.
The CB shall identify the top management having overall authority and responsibility for each of the following:

a) development of policies and establishment of processes and procedures relating to its operations:
b) supervision of the implementation of the policies, processes and procedures;
c) ensuring impartiality;
d) supervision of its finances;
e) development of MS certification services and schemes;
f) performance of audits and certification, and responsiveness to complaints;
g) decisions on certification;
h) delegation of authority to committees or individuals, to undertake defined activities on its behalf;
i) contractual arrangements;
j) Provision of adequate resources for certification activities.

The CB shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification activities.

6.2 Operational control

The CB shall have a process for the effective control of certification activities delivered by branch offices, partnerships, agents, franchisees, etc. irrespective of their legal status, relationship or geographical location. The CB shall consider the risk that these activities pose to the competence, consistency and impartiality of the CB.

The CB shall consider the appropriate level and method of control of activities undertaken including its processes, technical areas of CB operations, competence of personnel, lines of management control, reporting and remote access to operations including records.

7 Resource requirements
7.1 Competence of personnel

The CB shall have the following processes:

- To ensure that personnel have appropriate knowledge and skills relevant to the types of management systems (e.g. QMS, FSMS, EMS) and geographic areas in which it operates.
- To determine the competence criteria for whole CB personnel involved in the certification process.
- To perform initial evaluation of personnel competence, and ongoing monitoring of competence and performance of personnel, the CB shall demonstrate that its evaluation methods are effective.

The term „technical area" of competence mentioned in ISO\IEC 17021-1, shall be according to the identified categories in the Annex A (ISO\TS 22003). The certification functions for which the competence shall be identified are presented in the Annex C (ISO\TS 22003).

The competence criteria included in Annex C (ISO\TS 22003) shall form the basis for the determination of criteria for each category. Competence criteria may be generic or specific. The competence criteria described in the ISO\IEC 17021-1, Annex A, should be considered generic.

Note 1 – Competence criteria identified in Annex C (ISO\TS 22003) are associated to the criteria for the personnel of CB which certify FSMS.

Note 2 – Annex D provides guidelines for CB_{FSMS} on many certification functions identified in the Annex A (ISO\IEC 17021-1), for which competence criteria shall be determined for the personnel involved in the audit or certification activities of a FSMS.

Note 3 – Qualifications and experience may be considered as a part of criteria; however, the competence is not based only on this, because it's important to ensure that a person can demonstrate the capacity to apply his knowledge and specific skills, obtained after completing a qualification or having a certain stage of industrial experience.

The CB shall have documented processes for the initial competence evaluation and ongoing monitoring of competence and performance of all personnel involved in the performance of audits and certification of FSMS.

The evaluation process shall include, especially, individual knowledge evaluation regarding food safety, including specific knowledge of preliminary programs and risks for food safety related to categories within which operate each personnel of CB.

The CB shall have access to the necessary technical expertise for advice on matters directly relating to certification activities for all technical areas, types of management systems.

A number of possible evaluation methods that can be used to evaluate the competence of persons are described in the Annexes B, C and D of SM SR EN ISO\IEC 17021-1:2015.

7.2 Personnel involved in the certification activities

The MS certification body shall have sufficient competent personnel for managing and supporting the type and range of audit programmes and to maintain records regarding the knowledge of obligations, responsibilities and authorities of each person involved in the certification process, ***including relevant knowledge in accordance with the categories identified in the Annex A (ISO/TS 22003).***

CB shall:

- have defined processes for:
  - ✓ selecting,
  - ✓ training,
  - ✓ formally authorizing auditors,
  - ✓ Selecting and familiarizing technical experts.

The initial competence evaluation of an auditor shall include the ability to apply required knowledge and skills during audits, as determined by a competent evaluator observing the auditor conducting an audit.

CB must:

- Have a process to achieve and demonstrate effective auditing.
- Ensure that auditors (and, where needed, technical experts) are knowledgeable of its audit processes, certification requirements and other relevant requirements and that they have access to an up-to-date set of documents.
- Identify training needs and shall offer or provide access to specific training.
- Demonstrate that the group or individual that takes the decision understand the applicable standard and to demonstrate their competence to evaluate the outcomes of the audit processes including related recommendations of the audit team.
- monitor each auditor considering each type of management system to which the auditor is deemed competent, through a combination of types of evaluation:
  - ✓ on-site evaluation,
  - ✓ review of audit reports,
  - ✓ Feedback from clients or from the market.
- Periodically evaluate the performance of each auditor.

7.3 Use of individual external auditors and external technical experts

The CB shall require external auditors and external technical experts to have a written agreement relating to confidentiality and impartiality and to notification of the CB of any existing or prior relationship with any organization they may be assigned to audit.

7.4 Personnel records

The CB shall maintain up-to-date personnel records, including relevant qualifications, training, experience, affiliations, professional status and competence. This includes management and administrative personnel in addition to those performing certification activities.

7.5 Outsourcing

The CB shall have a process in which it describes the conditions under which outsourcing may take place. The certification body shall have a legally enforceable agreement covering

the arrangements, including confidentiality and conflicts of interests, with each body that provides outsourced services.
The CB shall not subcontract the decision.

The CB shall:

a) take responsibility for all activities outsourced to another body;
b) ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the CB and also to the applicable provisions of this part of ISO/IEC 17021-1, including competence, impartiality and confidentiality;
c) Ensure that the body that provides outsourced services, and the individuals that it uses, are not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised.

The CB shall have a process for the approval and monitoring of all bodies that provide outsourced services used for certification activities, and shall ensure that records of the competence of all personnel involved in certification activities are maintained.

8 Information requirements
8.1 Public information

The CB shall maintain and make public information about:

a) Audit processes;
b) Processes for granting, refusing, maintaining, renewing, suspending, restoring, withdrawing certification, expanding, or reducing the scope of certification;
c) Types of MS and certification schemes in which it operates;
d) The use of the CB's name and certification mark or logo;
e) Processes for handling requests for information, complaints and appeals;
f) Policy on impartiality.

The CB shall provide upon request information about:

a) Geographical areas in which it operates;
b) The status of a given certification;
c) The name, related normative document, scope and geographical location for a specific certified client.

Information provided by the CB to any client or to the marketplace, including advertising, shall be accurate and not misleading.

8.2 Certification documents

The certification body shall provide by any means it chooses certification documents to the certified client.

The certification documents should identify in detail the certificated activities, referring to the categories and subcategories; see the Table A.1 (ISO/TS 22003).

The certification document(s) shall identify the following:

a) the name and geographical location of each certified client (or the geographical location of the headquarters and any sites within the scope of a multi-site certification);
b) the effective date of granting, expanding or reducing the scope of certification, or renewing certification which shall not be before the date of the relevant certification decision;

c) the expiry date or recertification due date consistent with the recertification cycle;
d) a unique identification code;
e) the management system standard and/or other normative document, including indication of issue status (e.g. revision date or number) used for audit of the certified client;
f) the scope of certification with respect to the type of activities, products and services as applicable at each site;
g) the name, address and certification mark of the CB; may be used other marks (e.g. accreditation symbol, client's logo);
h) any other information required by the standard and/or other normative document;
i) In the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.

8.3 Reference to certification and use of marks

The CB shall have rules governing any MS certification. This mark shall not be used on a product nor product packaging nor in any other way that may be interpreted as denoting product conformity.
The CB shall not permit its marks to be applied by certified clients to laboratory test, calibration or inspection reports or certificates.
The CB shall have rules governing the use of any statement on product packaging or in accompanying information. The statement shall include reference to:

- ✓ identification of the certified client;
- ✓ the type of MS and the applicable standard;
- ✓ The CB issuing the certificate.

The CB shall through legally enforceable arrangements require that the certified client:

a) conforms to the requirements of the CB when making reference to its certification status in communication media such as the internet, brochures or advertising, or other documents;
b) does not make or permit any misleading statement regarding its certification;
c) does not use or permit the use of a certification document or any part thereof in a misleading manner;
d) upon withdrawal of its certification, discontinues its use of all advertising matter that contains a reference to certification;
e) amends all advertising matter when the scope of certification has been reduced;
f) does not allow reference to its MS certification to be used in such a way as to imply that the CB certifies a product (including service) or process;
g) does not imply that the certification applies to activities and sites that are outside the scope of certification;
h) Does not use its certification in such a manner that would bring the CB and/or certification system into disrepute and lose public trust.

The CB shall exercise proper control of ownership and shall take action to deal with incorrect references to certification status or misleading use of certification documents, marks or audit reports.

The CB shall identify in detail what activity is certified, referring to the categories and subcategories see the Table A.1 (ISO/TS 22003).

8.4 Confidentiality

The CB shall have policy, agreements to ensure confidentiality at all levels.
The CB shall inform the client, in advance, of the information it intends to place in the public domain. All other information, except for information that is made publicly accessible by the client, shall be considered confidential.
Information about a particular certified client or individual shall not be disclosed to a third party without the written consent of the certified client or individual concerned.
When the certification body is required by law or authorized by contractual arrangements to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided.
Information about the client from sources other than the client shall be treated as confidential, consistent with the CB's policy.
Internal and external personnel shall keep confidential all information obtained.
The CB shall have processes and where applicable equipment and facilities that ensure the secure handling of confidential information. The CB shall inform the client about the confidential information disclosure to other bodies (e.g. accreditation body).

8.5 Information exchange between a CB and its clients

The CB shall provide information to its clients on the following:

a) a detailed description of the certification activity;
b) the normative requirements for certification;
c) information about the fees;
d) the certification body's requirements for clients to:
    1) comply with certification requirements;
    2) make all necessary arrangements for the conduct of the audits, including provision for examining documentation and the access to all processes and areas, records and personnel;
    3) make provisions, where applicable, to accommodate the presence of observers (e.g. accreditation assessors or trainee auditor);
e) documents describing the rights and duties of certified clients, including requirements, when making reference to its certification;
f) Information on processes for handling complaints and appeals.

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

The CB shall have legally enforceable arrangements to ensure that the certified client informs the certification body, immediately, 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 MS;
e) Major changes to the MS and processes.

The CB shall document the undertaken actions for each above mentioned change and to take action as appropriate.

9 Process requirements
9.1 Pre-certification activities

Application

The CB shall require an authorized representative of the applicant organization to provide the necessary information to enable it to establish the following:

a) the desired scope of the certification;
b) relevant details of the applicant organization as required by the specific certification scheme, including its name and the address(es) of its site(s), its processes and operations, human and technical resources, functions, relationships and any relevant legal obligations;
c) information on outsourced processes used by the organization that will affect conformity to requirements;
d) the standards or other requirements for which the applicant organization is seeking certification;
e) Consultancy relating to the MS to be certified has been provided and, if so, by whom.

According to IAF MD 1:2018, on-demand, the Certification Body must obtain the necessary information about the requesting organization in order to:

- confirm that a single management system is implemented throughout the organization;
- determine the scope of the management system being managed and the required certification scope and, if applicable, the sub-areas;
- understand the legal and contractual arrangements for each location;
- understand "what and when takes place", e.g. processes/ actions provided at each location and to identify its headquarters;
- determine the degree of centralization of the process / activity that is provided to all locations (eg purchase);
- determine the interfaces between different locations;
- determine which locations could be applicable to sampling (ie where very similar processes / activities are offered) and those that are not eligible;
- take into account other relevant factors (see also IAF MD 4, IAF MD 11: IAF mandatory document applicabilty of ISO/IEC 17021-1 for Integrated Management System (IMS), ISO/IEC TS 17023);
- determine the audit time for the organization;
- determine the required competence audit team, and
- identify the complexity and scale of processes/ activities (eg one or more) covered by the management system.

CB should use Appendix A (ISO / TS 22003) to define the exact scope of the organization requesting SMSA certification. The OC should not exclude some of the activities, processes, products or services from the industry when such activities, processes, products or services may have an impact on the food safety of finished products as defined in the certification area

Application review

The CB shall perform a review of the application and supplementary information for certification to ensure that:

a) the information about the applicant organization and its management system is sufficient to develop an audit programme;
b) any known difference in understanding between the CB and the applicant organization is resolved;
c) the CB has the competence and ability to perform the certification activity;
d) The scope of certification sought, the site(s) of the applicant organization's operations, time required to complete audits and any other points influencing the certification activity are taken into account (language, safety conditions, threats to impartiality etc.).

The CB shall have a process for choose the day, hour and season for audit so that the audit team be able to audit the organization, operating on a representative number of production lines, categories and subcategories covered by the certification scope.

When the certification body declines an application for certification, the reasons for declining an application shall be documented and made clear to the client. If the CB accept the application for certification, the CB shall determine the competences it needs to include in its audit team and for the certification decision.
The competence of the audit team and of the persons who take the certification decision shall be in accordance with the requirement from the Annex A of the reference standard.

For the transfer of Certified Management Systems under accreditation, the OC should use documented procedures to provide the minimum criteria required for the transfer of certification in accordance with the provisions of IAF MD 2:2007 - IAF Mandatory Document for the Transfer of Management System Certifications Issued under Accreditation. This document is mandatory for the consistent application of ISO / IEC 17021-1. All requirements of ISO / IEC 17021-1 continue to apply and this document does not replace any of the requirements of this standard

Audit

9.1.3 Audit Program

The CB shall develop an audit programme for the full certification cycle in order to clearly identify the audit activity/activities required to demonstrate that the client's MS fulfils the requirements for certification to the selected standard(s) or other normative document(s).
The audit programme for the initial certification shall include a two-stage initial audit, surveillance audits in the first and second years following the certification decision, and a recertification audit in the third year prior to expiration of certification. The first three-year certification cycle begins with the certification decision.
The audit programme shall consider the following aspects:

- ✓ the size of the client's organization;
- ✓ the scope;
- ✓ the complexity of MS;
- ✓ products and processes;
- ✓ demonstrated level of MS effectiveness;
- ✓ The results of any previous audits.

The following additional items can be considered when developing or revising an audit programme:

- ✓ complaints received by the certification body about the client;
- ✓ combined, integrated or joint audit;
- ✓ changes to the certification requirements;
- ✓ changes to legal requirements;
- ✓ changes to accreditation requirements;
- ✓ relevant interested parties' concerns.

Concurrently, as per IAF MD 1: 2018, the audit program should at least include or refer to the following:
• the processes / activities provided at each location;

• identifying those locations that are required to be sampled and which are not;

• identifying locations that are covered by sampling, and which are not.

When establishing the audit program, the Certifying Body must provide sufficient additional time for activities that are not part of the calculated hearing time, such as travel, communication between audit team members, post-audit meetings, etc., due to the specific configuration of organization to be heard.

Note: Remote audit techniques could be used provided the processes to be audited are of such a nature that remote auditing is appropriate (see ISO / IEC 17021-1 and IAF MD 4:2018).

Where multi-member audit teams are used, it is the responsibility of the Certifying Body, in collaboration with the team leader, to identify the required technical competence for each part of the audit and for each location and to allocate the appropriate team members for each part of the audit.

Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.

Where the CB is taking account of certification already granted to the client and to audits performed by another CB, it shall obtain and retain sufficient evidence, such as reports and documentation on corrective actions, to any nonconformity.
The CB shall, based on the information obtained, justify and record any adjustments to the existing audit programme and follow up the implementation of corrective actions concerning previous nonconformities.
Where the client operates shifts, the activities that take place during shift working shall be considered when developing the audit programme and audit plans.

If the client is seeking certification of integrated management systems (ISO 9001 and ISO 22000), the CB shall have procedures in accordance with IAF MD 11:2019 – IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated management systems. This document is mandatory for the application of ISO/IEC 17021-1 by the certification bodies for planning and performing audits of integrated management systems (IMS). All the requirements of ISO/IEC 17021-1 are applicable. This document does not add additional requirements and not invalidate any requirement of ISO/IEC 17021-1.

9.1.4 Determining the audit duration

When determining the duration of the audit, the OC should take into account the requirements of IAF MD 1: 2018 for calculating the audit duration.

The duration of the audit must be sufficient to perform an effective audit, regardless of the structure of the organization.

Unless prohibited by specific schemes, the reduction in audit time at a sampled location must not be more than 50%.

The CB should have documented procedures for determining the audit duration, and for each client, the CB should determine the time needed to plan and perform a complete and effective client SMSA audit. The audit time established by the certification body as well as the justification of the established duration or the method of determination must be recorded.

In determining the audit time, the CB shall consider, among other things, the following aspects:

- ✓ the requirements of the relevant MS standard;
- ✓ complexity of the client and its MS;
- ✓ technological and regulatory context;
- ✓ any outsourcing of any activities included in the scope of the MS;
- ✓ the results of any prior audits;
- ✓ size and number of sites, their geographical locations and multi-site considerations;
- ✓ the risks associated with the products, processes or activities of the organization;
- ✓ whether audits are combined, joint or integrated.

The duration of the management system audit and its justification shall be recorded.
The time spent by any team member that is not assigned as an auditor (i.e. technical experts, translators, interpreters, observers and auditors-in-training) shall not count in the above established duration of the management system audit.

9.1.5 Multiple Location Sampling

The OC must have a multi-location sampling program in accordance with IAF MD 1: 2018 - IAF Compulsory Document for Auditing and Certification of a Managed Management System by a Multi-Locality Organization. This document is mandatory for the consistent application of ISO / IEC 17021-1 clause 9.1.5. All the requirements of ISO / IEC 17021-1 continue to apply and this document does not replace any of the requirements of this standard. This mandatory document can also be used for food safety management systems. However, the specific requirements for multilocks are first those stipulated in ISO / TS 22003, such as:

When setting the required audit time for each location as required in 9.1.4, the CB shall consider the minimum duration needed for initial certification at the client headquarter in determining the audit time required for each site as is presented in the Table B.1.

The minimum audit time includes the audit stage 1 and stage 2 for initial certification, but does not include the audit preparation time and the spent time for drafting the audit report.

In order to avoid duplication, where another relevant MS is in place and certified by the same CB there is no need for additional audit (see Table B.1). In case of performing a combined audit, which involves the FSMS, the reduction of time required for the audit can be applied if it is justified and documented.

The minimum audit time is determined for a FSMS audit, 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. Annex B (ISO/TS 22003).

The minimum audit time required for each site of the organization where are manufactured products/services shall represent 50% of total minimum audit time.

When the site sampling is permitted, the sampled sites shall be selected before determining the time needed for audit. Therefore, the audit duration shall be calculated practically for every site, in accordance with the requirements of the Annex B (ISO/TS 22003).

If the scope of a specific client covers more than one category, the determination of the audit time shall be based on the longest audit duration recommended. For each HACCP study is required additional audit time (minimum 0,5 days/audit for each HACCP study).

The minimum audit time for a site, Ts , expressed in days, shall be calculated using the following formula:

$$T_S = (T_D + T_H + T + T_{MS} + T_{FTE})$$

where,
T_D - audit time, basic on site;
T_H – the number of audit days for additional HACCP studies;
T_{MS} – the number of audit days for the absence of a relevant management system;
T_{FTE} – the number of audit days in accordance with the number of employees.

The minimum audit time for initial certification

Category (see Annex A)	*T_D Audit time, basic on site (audit days)*	*T_H For each additional HACCP study*	*T_{MS} The absence of a certified relevant MS*	*T_{FTE} Number of employees*	*For each site additionally visited*
A	*0,75*	*0,25*	*0,25*	*from 1 to 19 = 0 from 20 to 49 = 0,5 from 50 to 79 = 1,0 from 80 to 199 = 1,5 from 200 to 499 = 2,0 from 500 to 899 = 2,5 from 900 to 1299 = 3,0 from 1300 to 1699 = 3,5 from 1700 to 2999 = 4,0 from 3000 to 5000 = 4,5 > 5000 = 5,0*	*50% of the on-site minimum audit time*
B	*0,75*	*0,25*			
C	*1,50*	*0,50*			
D	*1,50*	*0,50*			
E	*1,0*	*0,50*			
F	*1,0*	*0,50*			
G	*1,0*	*0,25*			
H	*1,0*	*0,25*			
I	*1,0*	*0,25*			
J	*1,0*	*0,25*			
K	*1,5*	*0,50*			

The minimum time for surveillance audit should represent one third of the initial certification audit time, with a minimum of 1 audit days (0.5 days/audit for the categories A and B). The minimum time for certification should be two thirds of the initial certification time with a minimum of 1 audit days (0.5 days/audit for the categories A and B). When the time is appropriately documented and justified , the reduction of audit time to minimum can be done in a less complex organization, taking into account the number of employees, size of organization and/or production volume or within the categories with a minimum initial audit time no more than 1.5 days/audit.

A multi-site organization is an organization that has a central function identified (hereinafter referred to a central office, but not necessarily the headquarter of the organization) where are planned certain activities of FSMS, controlled or managed like a network of sites where these activities are carried aut entirely or partially. Examples of possible multi-site organizations:

- ***organizations operating with franchises;***
- ***a production company with one or more manufacturing facilities and a network of sales offices;***
- ***services organizations with multiple sites providing similar services;***
- ***organizations with multiple branches.***

The CB may certify a multi-site organization in a single certificate, but then the following conditions apply:

a) all sites operate under one FSMS, centrally managed and controlled as it is defined in the clause 4 of ISO 22000:2005 or equivalent for other FSMS;
b) an internal audit was performed in each site during the year before certification;
c) audit findings in individual sites shall be considered as an indicator for the whole system and shall be implemented corrective actions accordingly.

Multi-site sampling is possible only for the organizations with more than 20 sites operating similar processes and only for the categories A, B, E, F and G (see the table A.1, ISO/TS 22003). This applies for both initial certification and for surveillance audits. The CB shall justify its sampling decision when it certifies multi-sites organizations.

When multi-site sampling is permitted for certification, the annual internal audit programme shall include all the organization sites.

Note: The risk is another aspect when are determined the sites sampling and can contribute to the increasing of samples level in accordance with the data from the table 1 (ISO/TS 22003).

If the CB grants the certification for multiple sites, the CB shall use a sampling programme to ensure an effective audit for the FSMS, where applicable:

- ***For organizations with 20 sites or less, all the sites shall be audited. The sampling for more than 20 sites shall be a ratio of 1 to 5 sites. All locations shall be chosen randomly so that after each audit, any unsampled location must not be inconsistent (not meet the requirements of ISO 22000 certification);***

- ***At least annually, the CB shall perform an audit for FSMS at the organization headquarter;***

- ***At least annually, the CB shall perform surveillance audits of a necessary number of sampled sites;***

- ***The audit findings of the sampled sites shall be considered as an indication of the whole system, and the corrective actions shall be implemented accordingly.***

The CB shall have a sampling programme of the client with multi-sites, in accordance with the requirements of the specific standard IAF MD 1:2018 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization. This document is mandatory for the consistent application of clause 9.1.5 of ISO/IEC 17021-1. All requirements of ISO/IEC 17021-1 continue to be applied and this document doesn't supersede any requirement of this standard. This mandatory document is not exclusively for QMS and EMS, but can also be used for other management systems.

When certification to multiple management system standards is being provided by the certification body, the planning for the audit shall ensure adequate on-site auditing to provide confidence in the certification.

9.2 Planning audits

9.2.1 Determination of objectives, scope and audit criteria

The CB shall determine the audit objectives, scope and criteria.
The audit objectives shall include the following:

- ✓ determination of the conformity of the client's MS, or parts of it, with audit criteria;
- ✓ determination of the ability of the MS to ensure the client meets applicable statutory, regulatory and contractual requirements;
- ✓ determination of the effectiveness of the MS;
- ✓ Identification of areas for potential improvement of the MS.

The audit scope shall describe the extent and boundaries of the audit, such as:

- ✓ sites,
- ✓ organizational units,
- ✓ Activities and processes to be audited.

Where the initial or re-certification process consists of more than one audit (e.g. covering different sites), the scope of an individual audit may not cover the full certification scope, but the totality of audits shall be consistent with the scope in the certification document.

The audit criteria shall be used as a reference against which conformity is determined, and Shall be include:

- ✓ the requirements of a defined normative document on MS;
- ✓ The defined processes and documentation of the MS developed by the client.

9.2.2 Selecting and designating the audit team

The CB shall have a process for selecting and appointing the audit team, including the audit team leader and technical experts, taking into account the competence needed to achieve the objectives of the audit and requirements for impartiality. If there is only one auditor, the auditor shall have the competence to perform the duties of an audit team leader applicable for that audit.

In deciding the size and composition of the audit team, consideration shall be given to the following:

- ✓ audit objectives, scope, criteria and estimated audit time;
- ✓ whether the audit is a combined, joint or integrated;
- ✓ the overall competence of the audit team needed to achieve the objectives of the audit;
- ✓ certification requirements (including any applicable statutory, regulatory or contractual requirements);
- ✓ language and culture.

The necessary knowledge and skills of the audit team leader and auditors may be supplemented by technical experts, translators and interpreters who shall operate under the direction of an auditor. Where translators or interpreters are used, they shall be selected such that they do not unduly influence the audit.

Auditors-in-training may participate in the audit, provided an auditor is appointed as an evaluator which shall be competent to take over the duties and have final responsibility for the activities and findings of the auditor-in-training.
The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities.

Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts.
Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives.

Before audit process shall be agreed by the CB and client the presence and justification:

- ✓ Observers the audit process
- ✓ The role of technical experts
- ✓ The presence or lack a guide

9.2.3 Audit Plan

The CB shall ensure that an audit plan is established prior to each audit which shall be appropriate to the objectives and the scope of the audit.

The audit plan shall at least include or refer to the following:

- ✓ the audit objectives,
- ✓ the audit criteria,
- ✓ the audit scope, including identification of the organizational and functional units or processes to be audited,
- ✓ the dates and sites where the on-site audit activities will be conducted, including visits to temporary sites and remote auditing activities, where appropriate (for the off-site audit, the CB shall have a documented procedure),
- ✓ the expected duration of on-site audit activities,

- ✓ The roles and responsibilities of the audit team members and accompanying persons (observers or interpreters).

In addition to the requirements of ISO / IEC 17021-1: 2015 clause 9.2.3, the Certifying Body should at least consider the following in the preparation of the audit plan:

- the domain of certification and subdomains for each location;
- the management system standard for each location, where multiple management system standards are considered;
- processes / activities to be audited;
- Audit time for each location
- assigned audit team

The tasks of the audit team include the following:

- ✓ examine and verify the structure, policies, processes, procedures, records and related documents of the client relevant to the management system standard;
- ✓ determine that these meet all the requirements relevant to the intended scope of certification;
- ✓ determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's management system;
- ✓ To inform the client, for its action, any inconsistencies between the client's policy, objectives and targets.

The audit plan shall be communicated and the dates of the audit shall be agreed upon, in advance, with the client.
The CB shall provide the name of and, when requested, make available background information on each member of the audit team.

The audit process and third party certification is presented in the Annex E of the document ISO/IEC 17021-1.

9.3 Initial certification

The initial certification audit, ***including FSMS,*** shall be conducted in two stages.
The CB shall request to the applicant organization provide detailed information on processing lines, HACCP studies and the number of shifts.

The stage 1
The objectives of stage 1 are to:

a) review the client's management system documented information and whether the **organization has identified the *PRPs appropiate to its activity (e.g.: regulatory and statutory requirements, customer requirements and certification schemes)***;

b) Evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage two. *If* ***FSMS includes appropriate processes and methods for identifying and evaluating management system of food safety hazards and for choosing and subsequent classification of control measures (combination);***

c) review the client's status and understanding regarding requirements of the standard:
   - ✓ to the identification of key performance,
   - ✓ significant aspects,
   - ✓ processes,
   - ✓ objectives,
   - ✓ Operation of the management system.

d) obtain necessary information regarding the scope of the MS, including:
   - ✓ the client's site(s),
   - ✓ processes and equipment used,
   - ✓ levels of controls established (particularly in case of multisite clients),
   - ✓ applicable statutory and regulatory requirements ***on food safety,***
   - ✓ ***FSMS is designed to achieve the organization's policy on food safety.***

e) review the allocation of resources for stage 2 and agree with the client ***and if the program implementation of FSMS justify the moving to audit stage 2;***

f) obtaining a sufficient understanding of the client MS and the on-site activities ***and if the validation, verification and improvement programs are in accordance with the requirements of the FSMS standard;***

g) The FSMS documents and arrangements regarding internal communications and with relevant suppliers, clients and stakeholders;

h) any additional documentation that need to be reviewed and / or information which need to be obtained in advance;

i) Evaluate if the internal audits and management reviews are being planned and performed, and if the level of implementation of the MS substantiates that, the client is ready for stage 2.

Additionally, according to IAF MD 1: 2018 during Stage 1, the audit team must complete the information in order to:

• confirm the audit program;

• the Stage 2 plan, taking into account the processes / activities to be audited at each location;

• confirm that the Stage 2 audit team has the necessary expertise.

In case if the organization has implemented a combination of control measures external developed at Stage 1 analyzes the documentation included in FSMS to determine whether the combination of control measures:

- ***is suitable for the organization,***
- ***was developed in accordance with ISO 22000 requirements, and***
- ***is kept up to date.***

Availability of relevant authorizations shall be checked when collecting information regarding the fulfillment of some regulated issues.

For FSMS, the audit stage 1 shall be performed at the client headquarter for fulfill the above mentioned objectives.

In exceptional circumstances, a part of the audit stage 1 may take place off-site and shall be fully justified. The evidences which demonstrates that the stage 1 objectives are fully realized shall be provided. The exceptional circumstances may include a very distant location, seasonal production.

Documented conclusions with regard to fulfillment of the stage 1 objectives and the readiness for stage 2 shall be communicated to the client, including identification of any areas of concern that could be classified as a nonconformity during stage 2.

Any part of the FSMS which is audited in audit stage 1 and was found that is fully implemented, effective and in accordance with the requirements may not require re-audit within the stage 2. In any case, the CB shall ensure that the parties of FSMS already audited continue to comply with the requirements of certification. In this case, the audit report of stage 2 shall include those findings and declare clearly that in audit stage 1, compliance has been established.

In determining the interval between stage 1 and stage 2, consideration shall be given to the needs of the client to resolve areas of concern identified during stage 1.

If any significant changes which would impact the MS occur, the CB shall consider the need to repeat all or part of stage 1 and the client shall be informed.

The interval between audit stages 1 and 2 shall not exceed 6 months. If it takes longer, stage 1 shall be repeated.

Audit Stage 2:
The purpose of stage 2 is to evaluate the implementation, including effectiveness of MS. The stage 2 shall take place at the site(s) of the client and shall include:

a) information and evidence about conformity to all requirements of the applicable MS standard or other ND;
b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets;
c) the client's MS ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
d) operational control of the processes;
e) internal auditing and management review;
f) Management responsibility for the client's policies.

Additionally, according to IAF MD 1: 2018, the audit team must document the processes audited at each visited location at the outcome of the initial audit. This information will be used to modify the audit program and the audit plans for further oversight audits.

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

9.4 Conducting audits

9.4.1 Generalities

The CB shall have a process for conducting on-site audits, which shall include an opening meeting and a closing meeting of the audit.

9.4.2 Leading the opening session

An opening meeting, shall be held with the client's management and, where appropriate, those responsible for the functions or processes to be audited. In the opening meeting, usually conducted by the audit team leader, is to provide a short explanation of how the audit activities will be undertaken. The degree of detail shall be consistent with the familiarity of the client with the audit process and shall consider the following:

- ✓ introduction of the participants, including an outline of their roles,
- ✓ confirmation of the scope of certification,
- ✓ confirmation of the audit plan, any changes, and about interim meetings,
- ✓ confirmation of formal communication channels between the audit team and the client,
- ✓ confirmation that the resources and facilities needed by the audit team are available,
- ✓ confirmation of matters relating to confidentiality,
- ✓ confirmation of relevant work safety, emergency and security procedures for the audit team,
- ✓ confirmation of the availability, roles and identities of any guides and observers,
- ✓ the method of reporting, including any grading of audit findings,
- ✓ information about the conditions under which the audit may be prematurely terminated,
- ✓ confirmation that the audit team leader is responsible for the audit and shall be in control of executing the audit plan,
- ✓ confirmation of the status of findings of the previous review or audit, if applicable,
- ✓ methods and procedures to be used to conduct the audit based on sampling,
- ✓ confirmation that, during the audit, the client will be kept informed of audit progress and any concerns,
- ✓ confirmation of the language to be used during the audit,
- ✓ Opportunity for the client to ask questions.

9.4.3 Communication during the audit

During the audit, the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client.

Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the audit team leader shall report this to the client and, if possible, to the certification body to determine appropriate action:

- reconfirmation or modification of the audit plan;
- changes to the audit objectives or audit scope, or
- termination of the audit.

The audit team leader shall review with the client any need for changes and report this to the CB.
In case of need to modify the audit scope which becomes apparent as on-site auditing activities progress, the audit team leader shall review with the client any need for changes and report this to the CB.

9.4.4 Obtaining and verifying information

The information shall be obtained by appropriate sampling and verified to become audit evidence. Methods to obtain information shall include:

a) interviews;
b) observation of processes and activities;
c) Review of documentation and records.

9.4.5 Identify and record audit findings

Audit findings summarizing conformity and detailing nonconformity shall be identified, classified and recorded to enable taking an appropriate decision.
Opportunities for improvement may be identified and recorded, unless prohibited by the requirements of a management system certification scheme.
A finding of nonconformity shall be recorded against a specific requirement of audit criteria, and shall contain a clear statement of the nonconformity, identifying in detail the objective evidence on which the nonconformity is based.
Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. It hasn't to suggest the cause and solution.

9.4.6 Prepare audit conclusions

The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client concerning audit evidence or findings, and unresolved points shall be recorded.
Prior to the closing meeting, the audit team shall:

a) review the audit findings, and any other appropriate information obtained during the audit;
b) agree upon the audit conclusions, taking into account the uncertainty internal in the audit process;
c) agree any necessary follow-up actions;
d) confirm the appropriateness of the audit programme or identify any modification required for future audits.

9.4.7 Conduct of the closing session

A closing meeting shall be conducted by the audit team leader and shall be held with the client's management and, where appropriate, those responsible for the functions or processes audited. The participation in the closing meeting should be recorded.

Purpose of the closing meeting:

- Presentation of audit findings;
- Recommendation regarding certification;
- Nonconformities shall be submitted so as to be understood, and agreed deadline for settlement.

The closing meeting shall be consistent with the degree of familiarity of client with audit process:

a) inform the client that the audit evidence obtained was based on a sample of the information thereby introducing an element of uncertainty;
b) the method and timeframe of reporting, including any grading of audit findings;
c) the CB's process for handling nonconformities including any consequences relating to the status of the client's certification;
d) the timeframe for the client to present a plan for correction and corrective action for nonconformities identified;
e) the CB's post audit activities;

f) Information about the complaint and appeal handling processes.

The client shall be given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved and the unsolved shall be recorded and referred to the CB.

9.4.8 Audit Report

The CB shall be provide a written report for each audit. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the CB. The audit team leader shall be responsible for audit report content. The audit report shall be refer to:

a) identification of the CB;
b) the name and address of the client and the client's representative;
c) the type of audit, the audit criteria and the audit objectives;
d) any deviation from the audit plan and their reasons;
e) any significant issues impacting on the audit programme;
f) the audit scope, particularly identification of the organizational or functional units or processes audited and the time of the audit;
g) identification of the audit team leader, audit team members and any accompanying persons;
h) the dates and places of the audit activities;
i) audit findings, reference to evidence and conclusions;
j) significant changes, if any, that affect the MS of the client since the last audit took place;
k) any unresolved issues, if identified;
l) where applicable, whether the audit is combined, joint or integrated;
m) a disclaimer statement indicating that auditing is based on a sampling process of the available information;
n) recommendation from the audit team;
o) the audited client is effectively controlling the use of the certification documents and marks;
p) Verification of effectiveness of taken corrective actions regarding previously identified nonconformities.

The report shall include information on PRPs sites used by the organization, methodology for analyzing hazards. The comments regarding food safety team and other relevant issues for FSMS.

Note: Documented conclusions in the first stage are not necessary to correspond to all the requirements of a comprehensive report.

The report shall contain the following information:
- a statement on the conformity and the effectiveness of the MS together with a summary of the evidence relating to:
  - ✓ the capability of the MS to meet applicable requirements and expected outcomes;
  - ✓ the internal audit and management review process;
- a conclusion on the appropriateness of the certification scope;
- confirmation that the audit objectives have been fulfilled.

9.4.9 Analysis of the causes of nonconformities

The CB shall require the client to analyze the cause and describe the specific correction and corrective actions taken, or planned to be taken, to eliminate detected nonconformities, within a defined time.
According to the provisions of IAF MD 1: 2018, where nonconformities, as defined in ISO / IEC 17021-1, at any individual location, either through the internal audit of the organization or through the audit performed by the Certifying Body, an investigation must be conducted to determine if the other locations could be affected. Therefore, the Certifying Body should require the organization to review nonconformities to determine whether it indicates a general system deficiency applicable to other locations. If this is found, corrective action is taken and checked at both the headquarters and individual affected locations.
If it is found not to do so, the organization must be able to demonstrate to the Certifying Body the justification to limit corrective tracking actions.
The Certifying Body should require proof of these actions and increase its sampling frequency and / or sample size until it ensures that control is restored.

At the time of the decision-making process, if a location has a major nonconformity, certification is denied to the entire organization with many locations of the locations listed, pending satisfactory corrective actions.

It is not acceptable that, in order to overcome the obstacle caused by the existence of a nonconformity in a single location, the organization tries to exclude from the scope the "problematic" location during the certification process.

9.4.10 Efficiency of corrective actions and corrective actions

The CB shall review the corrections, identified causes and corrective actions submitted by the client to determine if these are acceptable. The CB shall verify their effectiveness. The evidence obtained shall be recorded. The client shall be informed of the result of the review and verification and shall be informed if an additional full audit, or limited to documented evidence, is needed.

9.5 Certification decision

The CB shall ensure that the persons or committees that make the decisions for granting or refusing certification are different from those who carried out the audits.
The individual(s) appointed to conduct the certification decision shall:

a) have appropriate competence;
b) be employed by, or shall be under legally enforceable arrangement with either the CB.

The CB shall have a process to conduct an effective review prior to making a decision for granting certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification, including, that:

- the information provided by the audit team is sufficient with respect to the certification requirements and the scope for certification;
- for any major nonconformities, it has reviewed, accepted and verified the correction and corrective actions;
- for any minor nonconformities it has reviewed and accepted the client's plan for correction and corrective action.

The information provided for the certification decision shall include, as a minimum:

- ✓ the audit report;

- ✓ comments on the nonconformities and, where applicable, the correction and corrective actions taken by the client;
- ✓ confirmation of the information provided by used in the application review;
- ✓ confirmation that the audit objectives have been achieved;
- ✓ a recommendation to grant or not certification, together with any conditions or observations.

If the CB is not able to verify the implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of stage 2, the CB shall conduct another stage 2 prior to recommending certification.

The CB shall take the decision to renew the certification relying on the recertification audit results, as well as on the system review results during the certification period and on recevied complaints.

According to IAF MD 1: 2018, the certification document must reflect the certification scope and legal locations and / or entities (where applicable) covered by multi-site certification.

Certification documents must contain the name and address of all locations, reflecting the organization to which the certification documents refer. The scope or other reference to these documents should clarify that certified activities are performed by the locations on the list. However, if the activities of a location include only one subset of the organization's scope, the certification document must include the subdomain of the location. If temporary locations are displayed on the certification documents, these locations are identified as temporary.

If certification documents are issued for a location, they must include:

• That it is the management system of the entire organization that is certified;

• activities carried out for that specific legal location / entity covered by this certification;

• traceability with the primary certificate, e.g. a code;

• a statement stating that "the validity of this certificate depends on the validity of the principal certificate".

Under no circumstances can this certification document be issued in the name of the legal location / entity or suggest that this location / legal entity is certified (the certified one is the customer organization) and should not include a statement of compliance of the processes / activities location to the normative document.

The certification documentation will be wholly withdrawn if any of the locations do not meet the requirements to maintain the certification.

9.6 Maintaining certification

The CB shall maintain certification based on demonstration that the client continues to satisfy the requirements of the MS standard, based on a positive conclusion by the audit team leader without further independent review and decision, provided that:

a) for any major nonconformity or other situation that may lead to suspension or withdrawal of certification, the CB has a system that requires the audit team leader to report to the CB the need to initiate a review by competent personnel, different from those who carried out the audit, to determine whether certification can be maintained;
b) competent personnel of the CB monitor its surveillance activities, including monitoring the reporting by its auditors, to confirm that the certification activity is operating effectively.

9.6.2 Surveillance activities

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

Surveillance activities shall include on-site auditing of the certified client's MS'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 CB to the certified client on aspects of certification;
b) reviewing any certified client's statements with respect to its operations;
c) requests to the certified client to provide documented information and records;
d) other means of monitoring the certified client's performance.

The CB shall plan surveillance audits on-site. The plan shall include the following:

a) internal audits and management review;
b) a review of actions taken on nonconformities identified during the previous audit;
c) complaints handling;
d) effectiveness of the MS 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;
h) use of marks and/or any other reference to certification.

In accordance with the provisions of IAF MD 1: 2018, the supervision of organizations with many locations that can be sampled must be audited in accordance with the methodology outlined in section 6.1 of IAF MD 1: 2018. The on-site audit time should be calculated in accordance with clause 9.1.4 above.

Surveillance of multi-location organizations that can not be sampled according to the methodology outlined in section 6.1 of IAF MD 1: 2018, is based on auditing 30% of locations plus headquarters. The locations selected for the second supervision of a certification cycle should not normally include any location from which samples were taken as part of the first surveillance audit. The on-site audit time should be calculated in accordance with clause 9.1.4 above.

9.6.3 Recertification

A recertification audit shall be planned and conducted to evaluate the continued fulfilment of all of the requirements. The recertification audit shall include the review of previous surveillance audit reports and consider the performance of the MS.

The audit stage 1 can be conducted in situations where there have been significant changes to the MS, the organization, or the context in which the MS is operating. In the case when there are multi-sites or the organization is seeking certification based on more than one standard the planning shall ensure an adequate covering of the on-site audit.

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

a) the effectiveness of the MS in its entirely 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 MS in order to enhance overall performance;
c) the effectiveness of the MS with regard to achieving the certified client's objectives and the intended results of the respective MS (s).

For any major nonconformity, the CB shall define time limits for correction and corrective actions, which shall be implemented and verified prior to the expiration of certification.

The CB shall take the decision of renewal based on the recertification audit results, the results of MS review during the certification period and the received complaints from the certification users.

When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certification can be based on the expiry date of the existing certification.
The issue date on a new certificate shall be on or after the recertification decision.

Following expiration of certification, the CB can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted.

According to IAF MD 1: 2018, the recertification of organizations with many sampling locations must be audited in accordance with the methodology set out in section 6.1 of IAF MD 1: 2018. The on-site audit time should be calculated in accordance with clause 9.1.4 above.

The re-certification of organizations with many locations that cannot be sampled must be audited as an initial audit, ie all locations audited plus headquarters. The on-site audit and headquarters should be calculated in accordance with clause 9.1.4 above.

9.6.4 Special audits

The CAB must have contractual arrangements with its clients that allow it to perform special audits if the client organization is involved in an event, in the case of information that calls into question the effectiveness of the management system of the certified organization.

Scope extension

The CB shall, in response to an application for expanding 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.

Unannounced audits

The CB may conduct announced or unannounced audits of certified clients to investigate complaints, or in response to changes, or as follow up on suspended clients.

In such cases the CB shall:

a) describe and make known in advance to the certified clients the conditions under which such audits will be conducted;
b) 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.

9.6.5 Suspending, withdrawing or reducing the scope of certification

The CB 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 CB.
The CB shall suspend certification in cases when, for example:

- the client's certified MS has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the MS;
- the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
- at client request.

During the suspention period (not exceed 6 months) the MS certification is temporarily invalid. Failure to resolve the issues that have resulted in the suspension in a time established by the CB shall result in withdrawal or reduction of the scope of certification.
The CB shall reduce the scope of certification to exclude the parts not meeting the requirements, when the certified client has persistently or seriously failed to meet the certification requirements for those parts of the scope of certification.

9.7 Appeals

The CB shall have a documented process to receive, evaluate and make decisions on appeals.
The CB 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. Submission, investigation and decision on appeals shall not result in any discriminatory actions against the appellant.

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 need 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.

The CB receiving the appeal shall be responsible for gathering and verifying all necessary information to validate the appeal.
The CB shall acknowledge receipt of the appeal and shall provide the appellant with progress reports and the result of the appeal.
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.

The CB shall give formal notice to the appellant of the end of the appealshandling process.

The appeal procedure shall be available to the certified client.

9.8 Complaints

The CB shall be responsible for all decisions at all levels of the complaints handling process.
Submission, investigation and decision on complaints shall not result in any discriminatory actions against the complainant.
The CB 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 MS.
The CB 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.
The complaints-handling process shall include at least the following elements:

a) an outline of the process for receiving, validating, investigating the complaint, and for deciding what actions need 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.

The CB shall be responsible for gathering and verifying all necessary information to validate the complaint. The CB shall acknowledge receipt of the complaint, and shall provide the complainant with progress reports and the result of the complaint.
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.

The CB shall give formal notice of the end of the complaints-handling process to the complainant. The CB shall determine, together with the certified client and the complainant, whether and, if so to what extent, the subject of the complaint and its resolution shall be made public.

The complaints procedure shall be available to the certified client.

9.9 Client records

The CB shall maintain records on the audit and other certification activities for all clients.

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 of sites, as appropriate;
d) justification for auditor time determination;
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;
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;
k) audit programmes.

The CB 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.

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

10 Management system requirements for certification bodies
10.1 Options

The CB shall establish, document, implement and maintain a management system according to the requirements of ISO/IEC 17021-1. In addition, the CB shall implement a management system in accordance with either:

a) general requirements of general MS; or
b) MS requirements in accordance with ISO 9001.

10.2 Option A: General management system requirements

10.2.1 Generalities

The CB's top management shall:

- ✓ establish, document, implement and maintain an MS in accordance with ISO / IEC 17021-1;
- ✓ establish and document policies and objectives for their activity;
- ✓ provide evidence of commitment to the development and implementation of MS in accordance with ISO / IEC 17021-1;
- ✓ to ensure that policies are understood, implemented and maintained at all levels of the CB.

The CB's top management shall assign responsibility and authority for:

- ✓ ensuring that processes and procedures needed for the MS are established, implemented and maintained;
- ✓ Reporting to top management on the performance of the MS and any need for improvement.

10.2.2 Management system manual

All applicable requirements of this part of ISO/IEC 17021-1 shall be addressed either in a manual or in associated documents. The CB shall ensure that the manual and relevant associated documents are accessible to all relevant personnel.

10.2.3 Control of documents

The CB shall establish procedures to control the documents internal and external that relate to the fulfilment of this part of ISO/IEC 17021-1. The procedures shall define the controls needed to:

- ✓ approve documents for adequacy prior to issue;
- ✓ review and update where necessary and re-approve documents;
- ✓ ensure that changes and the current revision status of documents are identified;
- ✓ ensure that relevant versions of applicable documents are available at points of use;
- ✓ ensure that documents of external origin are identified and their distribution controlled;
- ✓ prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

10.2.4 Control of records

The CB shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfillment of this part of ISO/IEC 17021-1.

The CB 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.

10.2.5 Management review

The CB's top management shall establish procedures to review its MS at planned intervals to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this part of ISO/IEC 17021-1. These reviews shall be conducted at least once a year.
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,
c) safeguarding impartiality,
d) the status of corrective actions,
e) the status of actions to address risks,
f) follow-up actions from previous management reviews,
g) the fulfilment of objectives,
h) changes that could affect the MS,
i) appeals and complaints.

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

a) Improvement of the effectiveness of the MS and its processes,
b) Improvement of the certification services related to the fulfillment of this part of ISO/IEC 17021,
c) Resource needs,
d) Revisions of the organization's policy and objectives.

10.2.6 Internal audits

The CB shall establish procedures for internal audits to verify that it fulfils the requirements of ISO/IEC 17021-1 and that the management system is effectively implemented and maintained.

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.

Internal audits shall be performed at least once every year. The frequency of internal audits may be reduced if the CB can demonstrate that its MS continues to be effectively implemented according to this part of ISO/IEC 17021-1 and has proven stability.
The CB shall ensure that:

a) internal audits are conducted by competent personnel well informed on certification, auditing and the requirements of this part of ISO/IEC 17021-1,
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.

10.2.7 Corrective actions

The CB shall establish procedures for identification and management of nonconformities in its operations. The CB shall take actions to eliminate the causes of nonconformities in order to prevent recurrence.
The procedures shall define requirements for:

a) identifying nonconformities,
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,
g) reviewing the effectiveness of corrective actions.

10.3 Option B: Management system requirements in accordance with ISO 9001

The CB shall establish and maintain a MS, in accordance with the requirements of ISO 9001, which is capable to support and demonstrate the consistent achievement of the requirements of this part of ISO/IEC 17021 -1 described from clause 5 to 10.2 of this document.

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

For application of the requirements of ISO 9001, when developing its MS, the CB shall consider the credibility of certification and shall address the needs of all parties that rely upon its audit and certification services, not just its clients.

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

MOLDAC requirements regarding the performance indicators of the food safety management systems certification bodies

The National Accreditation Body in accordance with requirements of IAF MD 15 request from the CB FSMS the identification of performance indicators, and their reporting in the basis of a regular study, with subsequent completion of the form „Questionnaire for collecting the data regarding the activity of CB FSMS", code PR-04-F-58. This questionnaire is annexed to the form „Information provided by the CAB in order to conduct surveillance", code PR-04-F-41 and transmitted to MOLDAC before the surveillance or by case at the request of the national accreditation body.
The performance indicators presented in the form, code PR-04-F-58, shall contain the following requirements from the IAF MD 15:

1. The number of valid certificates
   - 1.1 the total number of valid certificates issued till the end of December of the preceding year, and the total number of valid certificates issued from 01 January of the reporting year until the date of surveillance evaluation;
   - 1.2 the number of certificates issued to the clients, for whom is available the following condition: one certificate which ensures one single site of the client;
   - 1.3 the number of certificates issued to the clients, for whom is available the following condition: one certificate which ensures multiple sites of the client;
   - 1.4 the number of certificates issued to the clients, for whom is available the following condition: many certificates which ensure a single site;
   - 1.5 the number of clients who are certified by the CB only for one MS.
2. The number of clients who are certified by the CAB for more than one MS;
3. The number of auditors;
4. The number of accepted transfers;
5. The number of remaining audits;
6. The number of allocated days per auditor.

The National Accreditation Body MOLDAC

MOLDAC evaluation team asses the fulfillment of the requirements of SM SR EN ISO\IEC 17021-1:2015 and SM ISO\TS 22003:2014 standards, the commission which recommends the accreditation and the MOLDAC director, till the decision taking, review the evidences of compliance with the requirements including, if the CB:

- ***has personnel with competences and skills specific for FSMS for performing the application review; identifying and implementing the PRPs, HACCP studies and legal requirements applicable to the food chain; identification of the requirements regarding the audit team; development of audit plan; implementation of normative documents relevant to the certification scope, categories and subcategories of food chain, Annex C (ISO\TS 22003);***
- ***has identified the specific knowledge and skills in relation to the food chain categories in accordance with the general competence specified in the table C.1, Annex C (ISO\TS 22003);***
- ***the personnel involved in the competence evaluation has, at least, equivalent competence to the functions in the evaluation process;***
- ***has defined the activity scope, which includes, at least, categories and subcategories according to the examples from the table A.1 of the Annex A. (ISO\TS 22003);***
- ***has established technical criteria for describing the competences of auditors for each category according to the table A.1 of the Annex A. (ISO\TS 22003);***
- ***has trained auditors for each category and subcategory;***

- ***has established a process which ensures that the accredited certification is not granted only for sectors, categories and subcategories for which the auditors are qualified;***
- ***has a list of qualified auditors for each sector, category and subcategory; this list shall be available;***
- ***has the capacity to demonstrate that has at least one certification application for each granted accreditation.***
- ***has developed procedure in order to respond to the applications from new sectors , categories and subcategories (when the CB didn't organize trainings for the auditors in this sectors).***
- ***The audit time is determined in accordance with the Annex B (ISO\TS 22003);***

The Table A.1 from the Annex A (ISO/TS 22003) can be divided in groups as follows:

1. ***Farming [A(AI + AII) + B(BI + BII)]***
2. ***Food and feed processing [C(CI+CII+CII+CIV) + D(DI+DII)]***
3. ***Catering (E)***
4. ***Retail, transport and storage [F(FI+FII) + G(GI+GII)]***
5. ***Auxiliary services (H+I+J)***
6. ***Biochemical (K)***

These 6 groups are established only for the accreditation process and can not be used by the CB for the certification process.

MOLDAC can not grant the accreditation for a certain category, without conducting at least an assisted evaluation of the certification activity from the group of which take part this category.

e.g. If a CB is seeking accreditation for the categories B and D, there shall be conducted two assisted evaluations.

If the CB is seeking accreditation for the categories A and B is sufficient to be conducted one assisted evaluation.

The requirement is applicable also for the accreditation extension. For the extension of only one category from a group already accredited, the assisted evaluation is not mandatory. The assisted evaluation is mandatory for the application of the category extension from a new group. These requirements are minimum MOLDAC may decide the need for more assisted evaluation for specific situations.

MOLDAC shall conduct at least one assisted evaluation in the group 2 (if this is covered by the accreditation granted to the CB) within each surveillance evaluation and at least an assisted evaluation for the rest of groups during one accreditation cycle.

An assisted evaluation can cover certain categories, if the CB may justify them in relation to the activities of audited organization.

During the evaluation for the purpose of initial accreditation or reevaluation for one or more categories, an assisted evaluation of an initial audit, stage 1 is recommended. At least one assisted evaluation should include the audit stage 1 during an accreditation cycle.

MOLDAC should ensure that during one accreditation cycle, the assisted evaluations are conducted in the sectors for which the CB obtained accreditation, where exist a high risk regarding the food products safety.

MOLDAC shall avoid the assistance of an audit at the same CB client and shall consider the results of previous observations in order to establish the strategy of assisted evaluations.

7. SYNTHESIS CHANGES

Changes were included on the following pages 1, 3, 4, 13, 15, 36, 38