MOLDAC REPUBLICA MOLDOVA	**NATIONAL ACCREDITATION CENTRE**

REQUIREMENTS FOR ACCREDITATION OF MANAGEMENT SYSTEM CERTIFICATION BODIES

according to SM SR EN ISO/IEC 17021-1:2015
and SN ISO/IEC 17021-3:2017

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Elaborated by	Verified by	Advised CT/ OCI	Approved by Director
Angela IGNAT	Larisa NOVAC	Minutes nr.17 from 07.07.2020	Eugenia SPOIALĂ

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1. PURPOSE

The purpose of this document is to describe the requirements for the accreditation of Management System Certification Bodies according to SM SR EN ISO/ IEC 17021-1:2015 and SM ISO/IEC 17021-3:2017, MOLDAC documents applicable to these standards in order to ensure a unified and consequent application.

2. SCOPE

This document is applied by the whole MOLDAC personnel involved in the process of CABs, and 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/IEC 17021-3:2017 - Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 3: Competence requirements for auditing and certification of quality management systems.

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

- IAF MD 1:2018	mandatory	IAF Mandatory Document for Audit and Certification of Management System Operated by a Multi-Site Organization
- IAF MD 2:2017	mandatory	IAF Mandatory Document for the Transfer of Certifications of Management Systems issued under accreditation
- IAF MD 4:2018	mandatory	IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
- IAF MD 5:2019	mandatory	Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management
- IAF MD 11:2019	mandatory	IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems

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

- IAF MD 17:2019 mandatory Witnessing Activites for the Accreditation of Management Systems Certification Bodies

- IAF ID 1:2014 informative IAF Informative Document for QMS Scopes of Accreditation

EA, IAF document applicable by MOLDAC:

- IAF MD 7:2010 mandatory Harmonization 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 the way how the accreditation bodies assess the competence management of the certification bodies in accordance with ISO / IEC 17021: 2011.

- IAF MD 12:2016 mandatory (application date 07.01.2016) 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. Key activities are defined in IAF/ILAC A5 Clause 7.5.

- IAF MD 15:2014 mandatory (application date 14.07.2016) 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 17:2019 mandatory Witnessing Activities for the Accreditation of Management Systems Certification Bodies

This document is mandatory for the consistent application of Clause 7.5.6, 7.7.3 of ISO/IEC 17011 on accreditation of Conformity Assessment Bodies (CABs) by NAB,

Quality Management Systems and Environmental Management Systems.

- IAF ID 1:2014 informative IAF Informative Document for QMS Scopes of Accreditation

This document is informative and provides guidance on the transition from ISO / IEC 17021: 2011 to ISO / IEC 17021-1: 2015. Management systems certification bodies need to comply with MOLDAC information document on the transition to ISO / IEC 17021-1: 2015.

- Rules and procedures of 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 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

- SM SR EN ISO/IEC 17021-1:2015 – Conformity assessment. Requirements for bodies auditing and certificating management systems. Part 1: Requirements.

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
OSHMS - Occupational Safety and Health Management Systems
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

Item numbers from this chapter correspond to numbers of elements from SM SR EN ISO/IEC 17021-1:2015.

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, analyze, 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

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.
CB shall evaluate its finances and sources of income and demonstrate that its impartiality will not be compromised by commercial, financial pressures or of any other nature.

CAB shall demonstrate that it has adequate arrangements for covering liability resulting from its activity.

Adequate arrangements mean:
- policy/insurance contract (insured value shall be correlated with the type, field and volume of its activity, based on risk analysis);
- Bank guarantees or provisions (established value should be correlated with the type, field and volume of its activity, based on risk analysis).

6 Structural requirements

6.1 Organizational structure and top management

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 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.

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 Personnel competence

CB shall have documented processes:

- To define technical domains for accreditation request, which do technical committees / persons who ensure technical expertise of CAB validate.
- To ensure that personnel have appropriate knowledge and skills relevant to the types of management systems (e.g. QMS, FSMS, and 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.

An auditor shall not be declared competent by a CAB only because another CAB (accredited) declared him/her competent, CAB shall present records on checking whether he/she meets its own competence criteria.

To determine competence criteria for the personnel involved in certification and audit, CB shall consider the requirements of SM ISO/ IEC 17021-3:2017 for QMS.

Competence of CB auditors shall correspond to Table A1 from SM SR EN ISO/IEC 17021-1 and articles 5 and 6 from SM SR EN ISO/IEC 17021-3 and is confirmed by CB through at least two assessment methods (see Annex B of SM SR EN ISO/IEC 17021-1:2015).

CAB shall demonstrate that:

- assessment methods chosen are adequate to established assessment criteria;
- it has records to demonstrate how the personnel was assessed and which was the result of assessment;
- It has records to demonstrate that all competence criteria were assessed.

A number of possible assessment 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.

CB managers involved in certification activity (audit and certification decision) shall meet at least the following competence criteria:

- be a graduate of a high education institution;
- to have basic knowledge on certification standards used by the body;
- To have knowledge on certification standards applicable to body (17000 series) and applicable EA/IAF/ISO guides.

No considered professional experience for technical expert consultancy activity carried out by them in the field of management system.

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.

7.2 Personnel involved in certification activities

MS certification body shall have sufficient competent personnel for managing and supporting the type and range audit programs and to maintain records regarding the knowledge of obligations, responsibilities and authorities of each person involved in the certification process.

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.

OB 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 technical experts

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 for audit.

7.4 Personnel records

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

CB shall have a process in which it describes the conditions under which outsourcing may take place. Certification body shall have a legally enforceable agreement covering the arrangements, including confidentiality and conflicts of interests, with each body that provides outsourced services.
CB shall not subcontract the decision.

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, 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.

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

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.

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

If CB performs certification activities in geographical area other than Republic of Moldova, information shall be also available in an international language (for example for countries EU members – English, for CIS countries – Russian).

8.2 Certification documents

Certification body shall provide by any means it choose certification documents to the certified client.

Certification document 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

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.

CB shall not permit its marks to be applied by certified clients to laboratory test, calibration or inspection reports or certificates.

CB shall have rules governing the use of any statement on product packaging or in accompanying information. The statement shall include reference:

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

CB shall through legally enforceable arrangements 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.

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.

8.4 Confidentiality

CB shall have policy, agreements to ensure confidentiality at all levels.
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.
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

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.

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.

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:

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.

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

9 Process requirements
9.1 Pre-certification activities

9.1.1 Application

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) Whether consultancy relating to the MS to be certified has been provided and, if so, by whom.

At application, Certification Body, according to IAF MD 1:2018, should receive necessary information on applicant organization, in order:

- confirm that there is implemented one management system in the entire organization;
- determine the scope of management system that is operated and requested certification scope and, if possible, sub-domains;
- understand legal and contract agreements for each site;
- understand “what and where happens”, i.e. processes/ actions provided at each location and for identification of head office;
- determine the degree of process/ activity centralization that are provided to all sites (ex. purchasing);
- determine interfaces from different sites;

- determine which sites could be applicable for sampling (i.e. where are provided very similar processes/activities) and which one are not eligible;

- take into account other relevant factors (see also IAF MD 4, IAF MD 5, IAF MD: 11 Mandatory Document for Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems (IMS), ISO/IEC TS 17023);

- determine auditing time for organization;

- determine the team (s) for auditing necessary competence; and

- Identify the complexity and extent of processes/activities (ex. one or more) covered by management system.

While determining the scopes requested by client for certification, management systems, certification bodies shall use IAF ID 1:2014 – IAF Informative Document for QMS Scopes of Accreditation. This document is informative and facilitates the application of clause 7.1.1 from ISO/IEC 17021 - 1 and clause 7.2.1 from ISO/IEC 17021 - 1. All ISO/IEC 17021 - 1 requirements are applicable, IAF ID 1:2014 does not replace either one of the requirements of this standard.

9.1.2 Application review

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 program;
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.).

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 A1 of the reference standard.

9.1.3 Audit program

CB shall develop an audit program for the full certification cycle in order clear 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 program 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 program 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 considered when developing or revising an audit program:

- ✓ 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.

At the same time, according to IAF MD 1:2018, audit program should at least include or make reference to the following:

- processes/activities provided at each site;
- identification of those sites, which are mandatory to be sampled, and which are not; and
- Identification of sites, which are covered by sampling, and which are not.

At the establishment of audit program, Certification Body should provide enough additional time for activities, which are not a part of calculated audit time, such as traveling, communication between audit team, meetings after audit, etc., due to specific configuration of organizations to be audited.

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

If there are used audit teams composed of many members, it is the responsibility of Certification Body, in collaboration with team leader, in order to identify technical competence necessary for each part of audit and for each site, and to allocate appropriate team member for each part of 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, 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 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 audit duration

While determining audit duration, CB should consider requirements of IAF MD 1: 2018 on calculation of audit duration.

Audit duration should be enough to perform an efficient audit, regardless of organization structure.

Unless is not prohibited by specific scheme, reduction of auditing time for a sampled site should not exceed 50%.

For example, 30% does IAF MD 5 allow the maximum reduction of auditing time, while 20% is considered maximum reduction allowed for unique management system processes carried out by head office and any potential centralized processes (ex. purchasing).

Auditing time for a chosen site, including elements of head office, if appropriate, should be calculated for each site using IAF documents (ex.: IAF MD 5 for quality and environment management systems, IAF MD 11 for integrated management systems) and, if necessary, any requirement from sector scheme applicable for man days.

CB must have documented procedures for determining the duration of the audit in accordance with IAF MD 5: 2019 - Document IAF mandatory for the duration of QMS, EMS and OSHMS audits. This document provides requirements for the application of paragraph 9.1.4 ISO / IEC 17021-1 for QMS, EMS and OSHMS audits. All requirements of ISO / IEC 17021-1 continue to be applicable; this document does not supersede any requirement of this standard. Although the number of staff (permanent, temporary or part-time) customer is the starting point for estimating the duration of the audit, it is not the only element of this calculation. He must be consider as one of the factors for determining the duration of the audit.

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 Sampling multiple locations

CB shall have a sampling programme of the client with multi-sites, in accordance with the requirements of the document IAF MD 1:2018 – IAF Mandatory Document for Audit and Certification of 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 apply and this document does not supersede any requirement of this standard. This mandatory document is not exclusively for QMS and EMS, but can also use for other management systems. However, the specific standard ISO/TS 22003 provides requirements for multi-sites.

When certification 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.

IAF MD 4: 2008 - IAF Mandatory Document for the use of Computer Assisted Auditing Techniques (TAAC) for Accredited Certification of Management Systems. This mandatory document provides a consistent application of ISO / IEC 17021-1 TAAC when used as part of the audit methodology. TAAC use is not mandatory, but if a certification body and its client opt to use TAAC, it is mandatory for him to comply with this document and be able to demonstrate compliance National Accreditation Body.

9.2 Planning audits

9.2.1 Determining audit objectives, fields and criteria

CB shall establish its audit objectives, field and criteria. 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 audit.

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 Selection and appointment of audit team

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 supplemented by technical experts, translators and interpreters who shall operate under the direction of an auditor. Where translators or interpreters are used, they shall select 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 that 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 made as the audit progresses to ensure achievement of the audit objectives.

Before audit the CB and client, the presence and justification shall agree process:

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

9.2.3 Audit plan

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).

Additional to the requirements of ISO/IEC 17021-1:2015, clause 9.2.3, Certification Body should at least consider the following while preparing audit plan:

- certification scope and sub-domains for each site;
- management system standard for each site, if are considered multiple management system standards;
- processes/activities to be audited;
- auditing time for each site; and
- Allocated 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 certification body 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

9.3.1 Initial certification audit

Initial certification audit, shall be conducted in two stages.

Audit Stage 1

Objectives of stage 1 are to:

a) Review the client's management system documented information.
b) Evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2.
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.

e) review the allocation of resources for stage 2 and agree with the client;
f) obtaining a sufficient understanding of the client MS and the on-site activities
g) 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.

Additional, according to IAF MD 1:2018 during Stage 1, audit team should complete information in order to:

- confirm audit program;
- plan for Stage 2, taking into account processes/activities to be audited at each site; and

- confirm that audit team of Stage 2 has necessary competence.

It is recommended that at least one part of stage 1 to be carried out at client's office.

Documented conclusions with regard to fulfilment 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.

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.

CB shall not accept the period between stage 1 and stage 2 of certification audit to be more than 6 months.
CB shall demonstrate the way of proceeding in such situations.

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.

Additional, according to IAF MD1:2018, at the result of initial audit, audit team should document processes that were audited at each visited site. These information will be used to modify audit program and plans for subsequent surveillance 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 General

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 Conducting opening meeting

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 checking information

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 Identification and recording 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.
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.

9.4.6 Preparing audit conclusions

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 Conducting closing meeting

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.

The aim of 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 sent to the CB.

9.4.8 Audit report

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 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 Nonconformities causes analysis

CB shall require the client to analyse 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 provisions of IAF MD 1:2018, if nonconformities, as defined in ISO/IEC 17021-1, at each individual site, either through organization's internal audit, or through audit performed by Certification Body, should be performed an investigation in order to determine if other sites could be affected. Therefore, Certification Body should request organization to revise nonconformities in order to determine whether they indicate or not a general deficiency of system applicable to other locations. If this is found that they do not proceed in such a way, organization should be able to demonstrate to Certification Body a justification to limit corrective follow-up actions.
Certification Body should request evidence of these actions and increase frequency of sampling and/or sampling's size until it ensures that the control is restored.

At the time of decision-making process, if a site has a major nonconformity, certification is refused to entire multiple-site organization of listed sites, pending satisfactory corrective actions.

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

9.4.10 Effectiveness of corrections and corrective actions

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

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.

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 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.

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 received complaints.

According to provisions of IAF MD 1:2018, certification document should reflect certification scope and sites and/or legal entities (where is the case) covered by certification of multiple sites.

Certification documents should contain name and address of all sites, reflecting the organization which certification documents refer to. Scope or other reference to these documents should clarify that certification activities are carried out by a site from the list. However, if activities of one site include only a sub-set of organization's scope, certification document should include site's sub-domain. If on certification documents are displayed temporary sites, these sites are identified as being temporary.

If certification documents are issued for one site, these should include:

- that these is the management system of entire organization that is certified;
- activities carried out for that specific site/ legal entity that are covered by this certification;
- traceability with main certification, ex. a code; and
- a statement declaring that "validity of this certificate depends on the validity of main certificate".

Under no circumstances, can this certification document be issued on the name of site/ legal entity or suggest that this site/ legal entity is certified (what is certified is client's organization), and should not include a conformity statement of processes/ activities of site to normative document.

Certification documentation will be entirely withdrawn if any of sites does not comply with provisions necessary for maintenance of certification.

9.6 Maintaining certification

9.6.1 General

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.

IAF MD 3: 2008 - IAF Mandatory Document for Advanced Surveillance and Recertification Procedures. This document provides requirements for Advanced Surveillance and Recertification Procedures (PASR) for consistent application of paragraph 9.1.1 of ISO / IEC 17021-1 to determine subsequent adjustments to the audit program. This document applies only for QMS and EMS in which IAF members have had experience of implementing previous PASR or methodologies. Using PASR is not mandatory, but if MOLDAC allow its bodies accredited certification body and its clients to opt for the use of PASR, the IAF, EA, MOLDAC requires certification bodies and its customers to comply with this document and be able to demonstrate their compliance personnel involved in the accreditation process of MOLDAC.

9.6.2 Surveillance activities

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.

According to provisions of IAF MD 1:2018, surveillance of multi-site organizations that cannot be sampled should be audited in conformity with methodology indicated in 6.1 of IAF MD 1:2018. Audit time for site should be calculated in accordance with the above clause 9.1.4.

Surveillance of multi-site organizations that cannot be sampled in accordance with methodology indicated in 6.1 of IAF MD 1:2018, is based on audit of 30% of sites plus head office. Sites selected for the second surveillance of a certification cycle, typically, should not include any site which sampling has been carried out from as a part of first surveillance audit. Audit time for site should be calculated in accordance with the above clause 9.1.4.

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 provisions of IAF MD 1:2018, recertification of multi-site organizations that can be sampled should be audited in conformity with methodology indicated in 6.1 of IAF MD 1:2018. Audit time for site should be calculated in accordance with the above clause 9.1.4.

Recertification of multi-site organizations that cannot be sampled should be audited as an initial audit, and namely all audited sites plus head office. Audit time for site and head office should be calculated according to the above clause 9.1.4.

9.6.4 Special audits

CAB shall have contractual arrangements with its clients which will allow the performance of special audits if organization-client is involved in an event, for example if there is information that questions the efficiency of certification body's management system.

Scope extension

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

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 Suspension, withdrawal or reduction of certification scope

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.
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 suspension 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

CB shall have a documented process to receive, evaluate and make decisions on appeals.
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;
c) tracking and recording appeals, including actions undertaken to resolve them;
d) ensuring that any appropriate correction and corrective action are taken.

CB receiving the appeal shall be responsible for gathering and verifying all necessary information to validate the appeal.
CB shall acknowledge receipt of the appeal and shall provide the appellant with progress reports and the result of the appeal.
The decision shall 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.
CB shall give formal notice to the appellant of the end of the appeals handling process.
The appeal procedure shall be available to the certified client.

9.8 Complaints

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.

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.
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 and methods:

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.

CB shall be responsible for gathering and verifying all necessary information to validate the complaint.
CB shall acknowledge receipt of the complaint, and shall provide the complainant with progress reports and the result of the complaint.
The decision shall 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.
CB shall give formal notice of the end of the complaints-handling process to the complainant.
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

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.

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.
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

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 General

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.

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. CB shall ensure that the manual and relevant associated documents are accessible to all relevant personnel.

10.2.3 Documents control

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 Records control

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.

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

10.2.5.1 General
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 fulfilment of this part of ISO/IEC 17021. These reviews shall be conducted at least once a year.

10.2.5.1 Review input elements
Management review input elements 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.

10.2.5.1 Review output elements

Management review outputs 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 fulfilment of this part of ISO/IEC 17021-1,
c) Resource needs,

d) Revisions of the organization's policy and objectives

10.2.5 Internal audits

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 program 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

CB shall establish procedures for identification and management of nonconformities in its operations. TCB 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

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 management systems certification bodies

National Accreditation Body in accordance with requirements of IAF MD 15 request from the CB MS 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 MS", 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.

6. MODIFICATIONS SYNTESIS

There have been included modification on the following pages: 1, 3-6, 8-10, 14, 16-17, 19, 26, 30-34.