



PC-MSC MANAGEMENT SYSTEMS CERTIFICATION SCHEME



1. Purpose and scope

The purpose of the program is to define the principles of management system certification. The reference document in the certification process is standard ISO 9001 „Quality Management Systems. Requirements”.

KSC POLAND Sp. z o.o., hereinafter referred to as the Certification Body, certifies quality management systems in the Republic of Poland and abroad.

Conducting the certification processes of quality management systems, the Certification Body does not subcontract any activities related to the process.

2. Legal and normative acts in the management systems certification area

The rules of certification processes for management, supervision and re-certification systems are based on the requirements of the documents below:

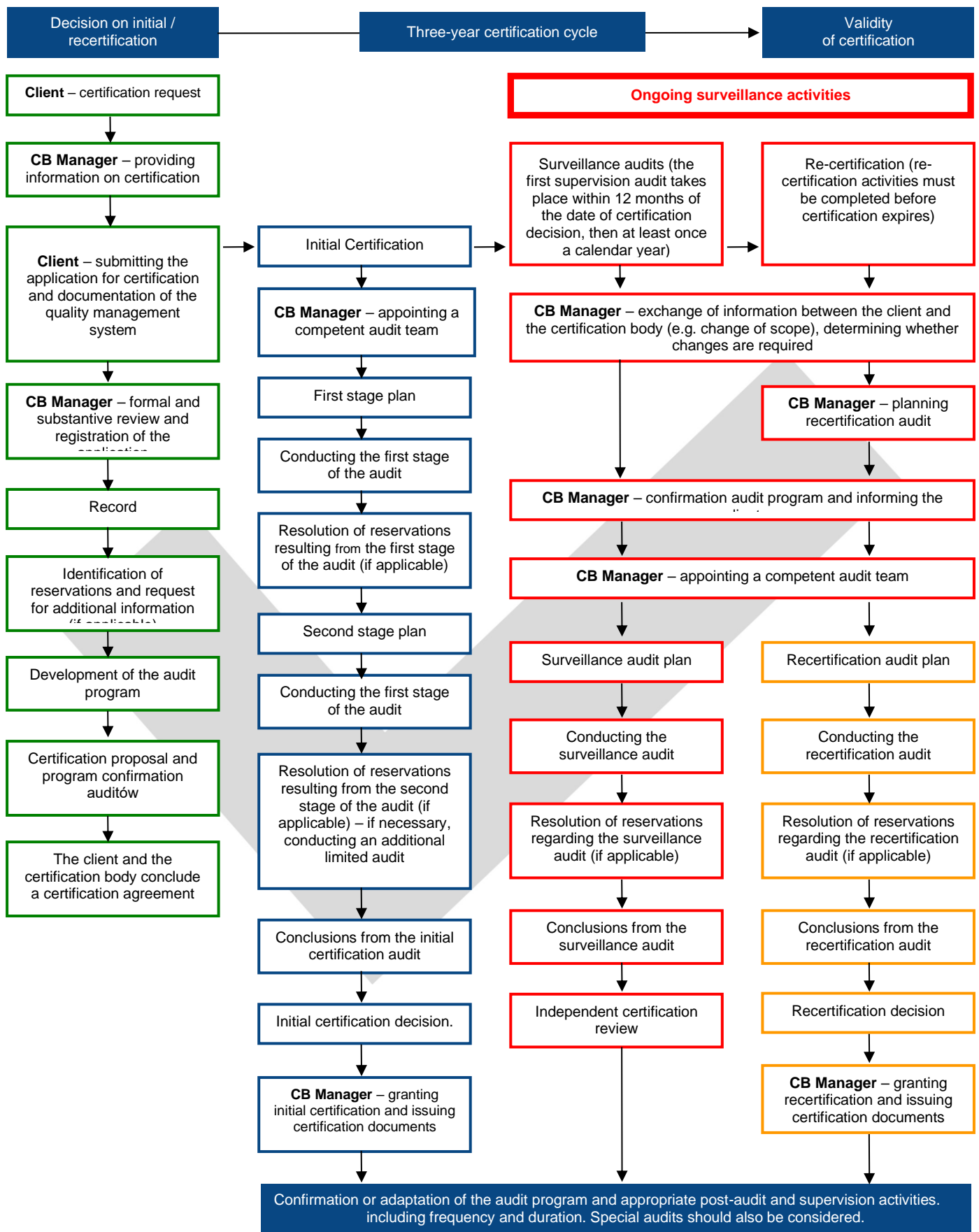
- 2.1. ISO/IEC 17021-1 – Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements,
- 2.2. ISO/IEC 17021-3 – Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems,
- 2.3. ISO 9001 – Quality Management Systems. Requirements,
- 2.4. ISO/IEC 17000 – Conformity assessment. Vocabulary and general principles,
- 2.5. IAF MD 1 – Mandatory Document for the Audit and Certification of a Management System Operated by Mutl-Site Organization,
- 2.6. IAF MD 2 – Mandatory Document for the Transfer of accredited Certification of Management Systems,
- 2.7. IAF MD 5 – Determination of audit time of quality and environmental management systems.

3. Requirements for organizations applying for certification

The condition of joining the certification for organizations applying for certification of the quality management system in the Certification Body is having an implemented and documented management system in accordance with the requirements of the ISO 9001 standard and documenting the functioning of the system for a period of at least three months.

The Certification Body issue certification when sufficient evidence is obtained that the quality management system arrangements have been implemented, are effective and will be maintained, and all non-conformities identified during the audit in the organization requesting certification have been corrected and corrective actions checked in accordance with the procedure established by Certification Body.

4. QMS certification process (scheme)



4.1. Preliminary / information procedure

The client interested in certification of the management system directs the inquiry to the Certification Body. This request may be in electronic, written, telephone or in person.

The CB Manager provides the client with information on the principles, fees and required documents regarding certification.

4.2. Start of the certification process

Client submits to the Certification Body an application for certification along with attachments containing supplementary information to the application, and documentation of the quality management system.

The application form is available on the website www.exksc.eu.

The Certification Body identifies, analyzes and assesses the risk of conflicts of interest during the certification process, reviews the application and supplementary information for certification to ensure that:

- a) information on the applicant client and his quality management system is sufficient to develop the audit program,
- b) all known differences in understanding issues between the Certification Body and the applicant client have been resolved,
- c) The Certification Body has the competence and capabilities to carry out certification activities,
- d) the scope of certification requested by the applicant is taken into account, location (s) of activity of the applicant client, time needed to carry out audits and all other elements affecting the certification activity (language, safety conditions, threats to impartiality, etc.),

As a result of reviewing the application, the Certification Body accepts or rejects the application for certification. If the application is rejected, the reason for its rejection is documented and explained to the applicant client.

In case of a positive result of the review of the application for certification, the client receives a price offer for the certification process.

After the client accepts the price offer, he receives two copies of the certification agreement specifying the obligations and rights of the parties as well as mutual timely and financial obligations.

After signing the agreement, the client delivers one copy to the Certification Body.

Based on the data contained in the application review, the CB Manger appoints a competent auditing team to carry out the certification process.

When deciding the size and composition of the audit team, they are taken into account:

- a) objectives, scope, audit criteria and estimated audit time;
- b) general competences of the audit team necessary to achieve the audit objectives;
- c) certification requirements (including applicable legal, regulatory or contractual requirements);
- d) language and culture.

The necessary knowledge and skills of the audit team can be supplemented by the participation of technical experts acting under the direction of the auditor.

The role of technical experts during audit activities is agreed with the client before the audit is carried out. The technical expert does not act as an auditor in the audit team. The technical experts are accompanied by an auditor.

Observers may also participate during the audit activities. Observers can be members of the client organization, consultants, observation staff of the accreditation body, regulators or other persons.

The presence and justification for the participation of observers during the audit activities is agreed with the client before the audit is carried out. The task of the audit team is to ensure that observers do not have significant influence or interfere with the conduct or outcome of the audit.

Tasks assigned to the audit team:

- a) examining and verifying the structure, policy, processes, procedures, records and documents related to the client in relation to a given quality management system,
- b) determining whether they meet all requirements in relation to the scope of certification requested,
- c) determining whether processes and procedures are established, implemented and effectively maintained to provide a basis of trust in the client's quality management system; and
- d) to communicate to the client, in order for him to take action, all the contradictions between the policy, goals and tasks.

The Certification Body develops an audit program for the entire certification cycle to clearly identify the audit activities required to demonstrate that the client management system meets the certification requirements. The audit program for the certification cycle covers all requirements for the management system.

If the client is working in a shift system, when developing the audit program, consider the actions that occur during shift work.

In cases where the Certification Body takes into account the certification already granted to the client and audits carried out by another certification body, it obtains and maintains evidence, such as reports and documentation regarding corrective actions for any non-compliance.

Based on the information obtained, justifies and records any changes to the existing audit program and tracks the implementation of corrective actions regarding previous non-conformities.

4.3. Initial certification (conducted in two stages)

4.3.1. First stage audit has the following objectives:

- a) review of documented client management system information,
- b) assessment of client-specific conditions and interviews with client staff to determine readiness for the second stage,



- c) reviewing the status of the client and his understanding of the requirements of the reference standard, especially in relation to the identification of key performance results or significant aspects, processes, objectives and operation of the management system,
- d) obtaining necessary information on the scope of the management system, including:
 - client location,
 - processes and equipment used,
 - levels of supervision measures established (especially for multi-branch clients),
 - applicable legal and regulatory requirements
- e) reviewing the allocation of resources to the second stage and agreeing on the details of the second stage with the client,
- f) focus on planning the second stage by achieving a sufficient understanding of the client's management system and its activities in a given location in the context of a management system standard or other normative document,
- g) assessment of whether internal audits and management reviews are planned and implemented, and whether the level of implementation of the management system justifies the client's readiness for the second stage.

Conclusions regarding the implementation of the objectives of the first stage and readiness for the second stage are documented and communicated to the client, including the identification of all areas where there were reservations that could be classified as non-compliance during the second stage. The applications do not have to meet all the requirements of the audit report.

4.3.2. Second stage audit *(at the client's location)*

It aims to assess the implementation and effectiveness of the client's quality management system and includes auditing:

- a) information and evidence of compliance with all the requirements of the relevant standard regarding the management system or other normative documents,
- b) monitoring, measuring, reporting and viewing achievements in relation to for key purposes and tasks (as expected in the relevant management system standard or other normative document),
- c) the ability of the client's management system and how it works to meet applicable legal, regulatory and contractual requirements,
- d) client's operational supervision over processes,
- e) internal audits and management reviews,
- f) management's responsibility for client policies.

When determining the distance between the first and second stages, the need for the client to resolve the reservations identified during the first stage is taken into account. The Certification Body may also need to check its preparation for the second stage. If there are any significant changes that could affect the management system, the Certification Body shall consider the need to repeat all or part of the first stage. The client is informed that the results of the first stage may lead to the postponement of the deadline or cancellation of the second stage.

4.4. Conducting audits

After prior arrangement with the organization of the audit date, the lead auditor prepare audit plan. Certification Body provides the organization with an audit plan a week before the planned audit containing information on the composition of the audit team in order to provide the basis for arrangements for conducting and planning audit activities.

The organization has the right to request in writing to change individual members of the audit team, e.g. in the event of a conflict of interest, unethical behavior, etc. The application should be submitted within 3 days of receipt information from the Certification Body. In justified cases, the Certification Body will change the members of the audit team.

At the beginning, the lead auditor conducts an opening meeting with the client's management and, if appropriate, with those responsible for the functions or processes audited, the purpose of which is to provide a brief explanation of how the audit activities will be carried out.

The lead auditor together with the client reviews each necessary change in the scope of the audit, which may arise as a result of on-site audit activities, and then presents these changes to the Certification Body.

If the available audit evidence indicates that the audit objectives are not achievable or indicate the existence of direct and significant risk (e.g. in terms of security), the lead auditor should present it to the client and the Certification Body for appropriate action. These activities may include reconfirmation or change of the audit plan, change of audit objectives or scope, or termination of the audit. The lead auditor is obliged to present to the Certification Body the results of the undertaken action.

The audit team obtains information through appropriate sampling and verification so that they can constitute audit evidence.

Methods for obtaining information should include:

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

Finally, the lead auditor conducts a closing meeting, at which he confirms with the organization (or not) that the scope of the organization's activities covered by the QMS is consistent with the content of the application. Also are presented, among others conclusions from the audit. The conclusions relate to the positive aspects of the system under assessment as well as possible comments and discrepancies. In case of nonconformities during the audit, the audit team issues a nonconformity card.

Each nonconformity must be related to one / several requirements of the reference standard or other document that contains certification requirements.

The client can ask questions. Any divergent opinions between the audit team and the client regarding the findings or conclusions of the audit should be discussed and, if possible, resolved. Any unresolved divergent opinions should be recorded and directed to the Certification Body.

The lead auditor is responsible for preparing the audit report and its content. The audit report contains accurate, concise and clear audit records to enable a reasoned certification decision to be made.

The Certification Body provides the client with an audit report prepared by the lead auditor. It is the client's responsibility to conduct a cause analysis and describe specific corrections and corrective actions taken or planned to be implemented to eliminate identified nonconformities within a specified period of time.

The Certification Body reviews the corrections, identified causes and corrective actions submitted by the client to determine if they are acceptable. In addition, it verifies the effectiveness of any corrections and corrective actions taken. The evidence obtained confirming the removal of the nonconformity are recorded. The client is informed about the results of the review and verification. If, in order to verify the effectiveness of corrections and corrective actions, an additional full audit will be required, an additional limited audit or documented evidence (to be confirmed during future audits), the client is informed.

If the implementation of the correction and corrective action regarding any major nonconformities cannot be verified within six months of the last day of the second stage of the audit, the second stage of the audit shall be carried out again before the certification recommendation is issued.

4.5. Certification decision

The information provided by the audit team to make a certification decision includes, as a minimum:

- a) audit report;
- b) comments on nonconformities and, where appropriate, the corrections and corrective actions taken by the client;
- c) confirmation of the information provided to the Certification Body used in the review of the application;
- d) confirmation that the audit objectives were achieved;
- e) a recommendation about issuing or not certification, including all conditions or observations.

Based on the assessment of audit findings and conclusions, as well as any other applicable information (e.g. publicly available information, client comments on the audit report), a decision is made to issue or refuse to issue a quality management system certificate.

The decision about refusal to grant a certificate is given to the client by the CB Manager along with the justification.

4.6. Certificate issue

The quality management system certificate is issued by the Certification Body for a period of 3 years from the date of the decision and cannot be transferred to third parties.

After settling all obligations towards the Certification Body, the client receives two copies of the certificate. The form of transferring the certificate is agreed individually.

Upon the transfer of the certificate, the client has the right to use the certificate in a manner consistent with the signed agreement and applicable regulations. The client has the right to make public that he has obtained the certificate and provide the scope of certification. The fact of having a certificate can be used by the client in advertising, but there can not be doubt, that the certificate concerns the management system, not the products he sells.

4.7. Maintenance of certification

During the period of validity of the certificate, the Certification Body supervises the issued certificate in order to monitor representative areas and functions covered by the scope of the system and track changes in the certified organization and its management system.

Surveillance activities include on-site audits assessing compliance of the certified client management system with specified requirements for the standard under which certification was granted.

Other surveillance activities may include:

- a) Certification Body inquiries to the certified client regarding various aspects of certification,
- b) reviewing all client statements in relation to his activities (e.g. promotional materials, website, etc.),
- c) requests that the client provide documented information (in any form),
- d) other ways to monitor the performance of the certified client.

The Certification Body conducts on-site surveillance audits (not whole management system) to maintain confidence that the certified quality management system still meets the requirements between audits for re-certification.

Each surveillance audit covers at least:

- a) internal audits and management reviews,
- b) review of actions taken in relation to nonconformities identified during the previous audit,
- c) handling complaints / appeals,
- d) effectiveness of the quality management system in terms of achieving the objectives of the certified client and the intended results of the management system,
- e) development of planned activities aimed at continuous improvement,
- f) continuous operational supervision,
- g) review of any changes

Surveillance audits are carried out at least once in calendar year, except for the years in which re-certification is to be carried out. The date of the first surveillance audit after the initial certification should not be later than 12 months from the date of the certification decision.

4.8. Re-certification

The Certification Body plans and conducts re-certification audits to confirm the constant compliance and effectiveness of the management system as a whole and its continuing suitability for the scope of certification. Re-certification audits are planned and carried out in a timely manner to enable timely extension of certification before the end of certification validity.

The re-certification audit takes into account the results of the quality management system functioning in the period covered by the certification and includes a review of reports from previous surveillance audits.

In situations where significant changes have occurred in the quality management system, or in the context in which the quality management system is operating (e.g. legislative changes), audit activities for re-certification may require the first stage of the audit.

In the case of certification by a Certification Body of a multi-division organization, in order to gain confidence in certification, audit planning will include the appropriate scope of the on-site audit.

The re-certification audit includes an on-site audit focused on:

- a) effectiveness of the management system as a whole in the light of internal and external changes, and its continuing suitability for the scope of certification,
- b) demonstrated commitment to maintaining effectiveness and improving the quality management system to improve the overall way of operating,
- c) effectiveness of the management system in terms of achieving the client's goals and the intended results of the management system.

In case when large nonconformity is identified during the re-certification audit, the Certification Body sets the time limits for correction and corrective actions. Activities should be implemented and verified before the expiration date of certification.

If the re-certification activities are completed successfully, before the expiry date of the current certification, the expiry date of the new certification is determined based on the expiry date of the current certification. The date of issue of the new certificate is the date of the decision on the re-certification or a later date.

If the Certification Body fails to complete the re-certification audit or is unable to verify the implementation of corrections and corrective actions regarding any major non-compliance before the expiration date of the current certification, then re-certification is not recommended and the validity of certification is not extended. The client is informed and the consequences are explained.

After the certification has expired, the Certification Body may resume certification within six months, provided that the re-certification activities that have not been completed are completed, otherwise it will carry out at least the second stage. The date of entry into force of the decision indicated on the certificate is the date of the decision of the re-certification, or the date after the decision has been taken, and the certification validity date is determined based on the previous certification cycle.

4.9. Special audits (*extending, suspending, withdrawing or reducing the scope*)

4.9.1. Extension

In response to an application for extending of the scope of already granted certification, the Certification Body conducts a application review to determine all audit activities necessary to make a decision to extend the scope. The extension can be carried out in conjunction with a surveillance audit or other date agreed with the client.

4.9.2. Audit with a short notification period

During the period of validity of management system certification, it may be necessary for the Certification Body to carry out an audit with a certified client with a short notification period, or without notification, to investigate complaints, assess changes in: legal, commercial, organizational, ownership, organizational structure and management status, address for contacts and places of business, scope of activity covered by a certified quality management system, major changes in the quality management system and processes, or further handling of suspended clients.

The CB Manager assesses the impact of the above factors for the certification granted and decides to conduct an audit with a short notice. The client is informed in writing about the date of the audit, audit team, audit plan and the justification for conducting it. In this case, the client is not able to raise objections regarding the composition of the audit team, therefore the CB Manager is particularly careful when determining its composition. In the event of refusal to undergo an audit with a short notice, the certificate is suspended (the client is informed).

4.9.3. Suspending, withdrawing or reducing the certification scope

Certificate suspension may be a consequence:

- a) the certified client management system permanently or seriously does not meet the certification requirements, including requirements regarding the effectiveness of the management system;
- b) the certified client does not allow supervision audits or recertification audits to be carried out with the required frequency;
- c) a certified client has voluntarily requested for suspension.

Along with the decision to suspended certificate, the Certification Body obliges the client to stop relying on the certificate. The certificate may be issue back as soon as the reasons for suspension cease to exist. The certificate may be issue back if the client whose certificate has been suspended provides information on meeting the conditions accompanying the suspension decision.

Failure to resolve by the client, within the time set by the Certification Body, the issues that caused the suspension results in withdrawal or limitation of the scope of certification. The certification suspension period may not exceed six months.

Reducing the scope of the Client's certification applies to exclude those parts that do not meet the requirements when the Client permanently or seriously fails to meet the certification requirements for those parts of the scope of certification.

Along with the decision to withdraw the certificate, the Certification Body obliges the client to cease to rely on the certificate and return the certificates.

5. Complaints and appeals

Certification Body clients have the right to appeal against a decision to refuse, withdraw, suspend or reduce the certification to the President of the Board within 14 days of receiving notification of the contested decision.

Submission, consideration and decision making on appeals do not result in any discriminatory action against the applicant.

Complaints are a source of information about the effectiveness of a client's certified management system. All complaints about the certified client are addressed in due time by the Certification Body to the client. It is recommended that after receiving the complaint, the certified client determine and, if appropriate, prepare a report on the cause of the complaint, taking into account previously established (or potential) factors within his quality management system.

The Certification Body is responsible for all decisions taken at all levels in dealing with appeals or complaints. Ensures that the decision resolving the appeal or complaint is taken or reviewed and approved by persons not involved in certification activities (assessment / certification decision) related to the application. In addition, in order to ensure that there is no conflict of interest, no personnel shall be appointed to review or approve the resolution of the appeal or complaint during the last two years or have been employed by the client submitting the appeal or complaint.

6. Protection of client information and property rights

Employees of the Certification Body are obliged to keep confidentiality with respect to all information they obtain in the course of performing their tasks in accordance with national law in a given scope (except for secrecy towards the competent authorities of the Member State in which the tasks are carried out). Property rights are protected.

Persons involved in the certification process ensure the confidentiality of all information related to the process. All information provided by clients are confidential and are not disclosed to a third party without the client's written consent. If the law requires disclosure of any information to a third party, the client is notified of the content of the disclosed information to the extent permitted by the relevant normative documents or legal provisions.

Confidentiality is also ensured through:

- *limited access to client documentation from the moment of application for certification up to the archiving stage,*
- *records of documentation created during the certification and surveillance process,*
- *archiving assessment evidence and all clients documentation provided during the certification process.*

7. Methodology for determining the duration of QMS audits and sampling rules in multi-branch organization certification processes.

- *Audit time is the time needed to plan and conduct a complete and effective audit of the client's management system*
- *The duration of all types of audits is the effective time measured by the number of audit days needed to carry out the activities.*

- *Audit duration for all types of audits includes on-site time at the client's premises and time outside of his department, devoted to planning, document review, communication with client staff and writing a report.*

The duration of all types of audits is calculated in accordance with the methodology in IAF MD 5 regarding the determination of management system audit time.

- *A multi-branch organization is defined as an organization with an identified central office (headquarters - but not necessarily the role of the main board of the organization) in which specific activities are planned, supervised or managed, and a network of local offices or branches in which these activities are performed in whole or in part.*

Certification audit, subsequent surveillance audits and reassessment audits are usually carried out in each branch of the organization to be covered by certification. However, if the organization's activity, subject to certification, is performed in a similar manner in various departments managed and supervised by that organization, the Certification Body may implement appropriate branch sampling procedures during the certification process and subsequent surveillance audits and reassessment.

Determining the conditions to be met by an organization in which sampling can be used, including the calculation of the sample size and duration of the audit, is based on the IAF MD 1 document on sampling rules in multi-branch organization certification processes.