POLISH CENTRE FOR
TESTING AND CERTIFICATION

www.pcbc.gov.pl

Rules of certification management systems
- Information for Organizations

DBC 14

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Contents

1. Introduction

These rules for management system certification are intended for Organizations applying for management system certification at Polskie Centrum Badań i Certyfikacji S.A. within the following scope:

- EN ISO 9001, QMS
- EN ISO 13485, MDMS

The rules also apply to the certification of integrated systems, which are a compilation of the above.

These rules are extracts from the procedures of PCBC S.A. - Management Systems Certification Department.

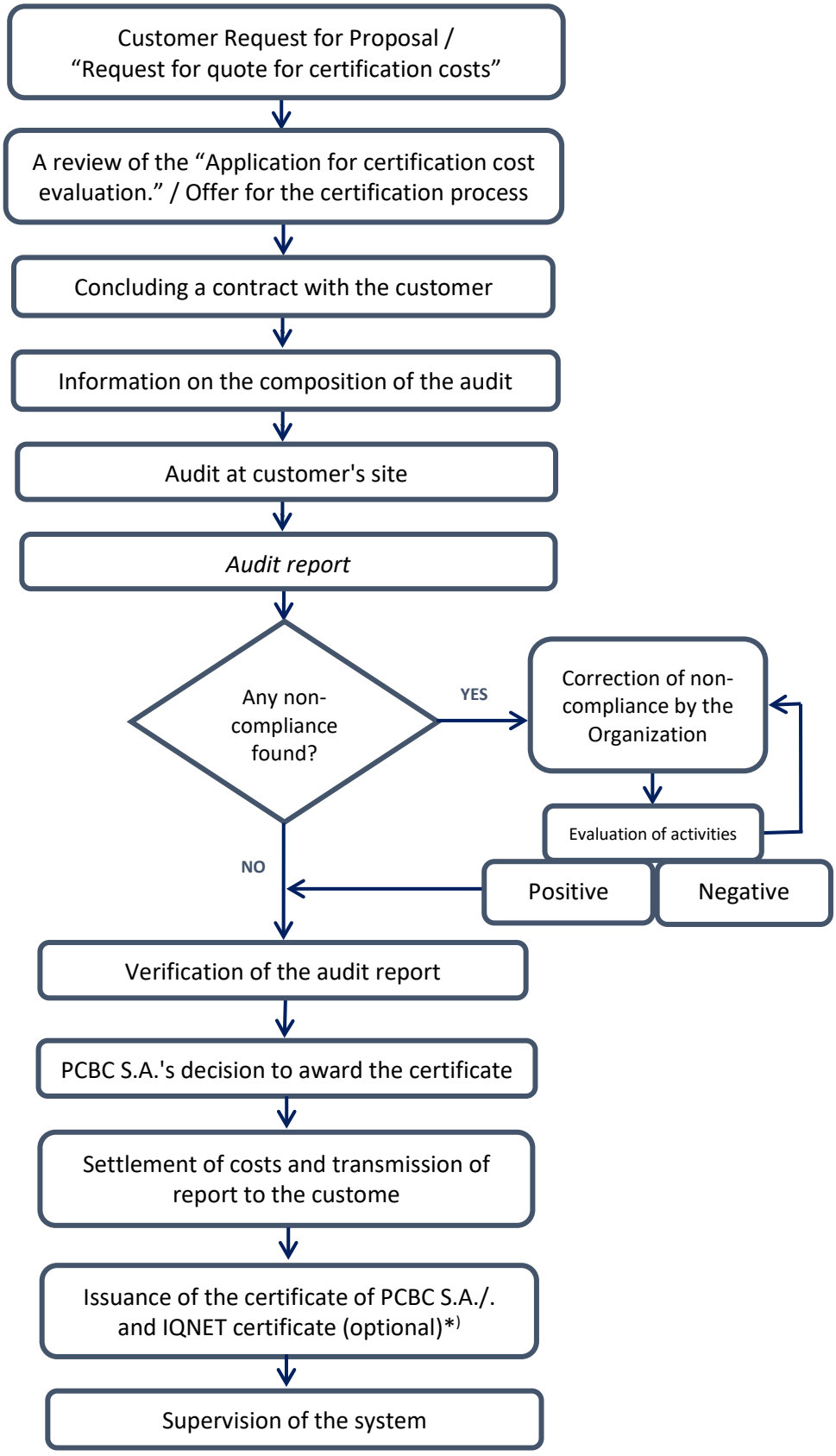
PCBC S.A. documents related to the certification process are available on the website (www.pcbc.gov.pl) and at the Organization's request at the PCBC S.A. headquarters. Other documents referred to in this document are available respectively: standards - Polish Committee for Standardization (www.pkn.pl); IAF documents - Polish Center for Accreditation (www.pca.gov.pl).

The principles of Management Systems Certification were developed based on the requirements of standards and documents:

- EN ISO 9000 Quality management systems - Fundamentals and terminology,
- PN-EN ISO/IEC 17021-1 Conformity assessment. Requirements for bodies providing audit and certification of management systems,
- PN-EN ISO/IEC 17021-3 Conformity assessment - Requirements for bodies providing audits and certification of management systems and certification of management systems - Part 3: Requirements for competence to audit and certify quality management systems,
- IAF MD 1 IAF mandatory document for auditing and certification of management systems of multi-site organizations,
- IAF MD 2 IAF Mandatory Document for the Transfer of Accredited Management Systems Certification,
- IAF MD 4 IAF Mandatory Document on the use of Information and Communication Technology (“ICT”) for audits/assessments,
- IAF MD 5 IAF Mandatory Document Setting audit time for quality, environmental and occupational health and safety management systems,
- IAF MD 9 IAF Mandatory Document Application of ISO/IEC 17021 to Medical Device Quality Management Systems (ISO 13485),
- IAF MD 11 IAF mandatory document on the application of ISO/IEC 17021-1 in audits of integrated management systems,
- IAF MD 28 IAF Mandatory Document for the submission of data to the IAF Database and their maintenance

Where this document refers to standards or other documents, it refers to their current editions.

2. The course of the management systems certification process and the main principles of IQNET certificate management



)** ***Information for Organizations receiving IQNET certification

As part of the certification agreement signed with PCBC S.A., it is possible for PCBC S.A. (IQNET member), in accordance with the following general rules, an IQNET certificate suitable for a given management system:

a) The IQNET Certificate is an attachment to a statement of recognition issued by PCBC S.A, based on the audit and certification process conducted by or under the leadership of PCBC S.A. The IQNET certificate is issued by PCBC S.A. on behalf of IQNET. IQNET's recognition is possible because trust has been established between IQNET members based on the results of peer evaluations, cooperative experience, the signed IQNET Member Agreement, which deals with mutual recognition of certificates.
b) The IQNET Certificate is issued and will be modified or withdrawn concurrently with the with the issuance and modification or withdrawal of the PCBC S.A. certificate.
c) The primary responsibility for issuing the IQNET certificate rests with PCBC S.A.
d) The procedures and conditions for issuing, modifying and withdrawing an IQNET certificate are in accordance with the in accordance with the principles described in the PCBC S.A. management systems certification documentation. and in the IQNET documentation.
e) In the event of termination of PCBC S.A.'s membership in IQNET, the IQNET certificate will be canceled and withdrawn by PCBC S.A. within 30 days, and IQNET certificate holders will be informed in writing (letter, e-mail with a copy to IQNET Headquarters) that the validity of the IQNET certificate has expired.

3. Customer inquiry / “Request for quote for certification costs / Review of „Request for quote for certification costs”

In response to the Client's inquiry, submitted as a “Request for quote for certification costs ” with attachments, which is posted on www.pcbc.gov.pl, PCBC S.A., conducts within 1 day a review of the aforementioned request for its correctness in terms of form and content in order to decide on the possibility of carrying out the certification process.

If the application is incomplete, PCBC S.A. requests the Client to supplement it. If the application is not supplemented within 14 days from the date of receipt of information about its incompleteness, the application is rejected.

Within max. 5 working days PCBC S.A. prepares an offer for the process of certification/re-certification/transfer of certification and sends it to the Client. In case of inability to carry out the process of certification/re-certification/transfer of certification, e.g. due to a conflict of interest, it informs the Client in writing.

The organization in the application is required to specify the scope of the expected certification.

The scope should be consistent with the document describing the scope of the Organization's management system, and should be formulated in an unambiguous and not misleading manner. The scope of certification should include the main processes, i.e. activities (e.g. design, production of products or provision of services to external customers). The scope of certification should not state supporting, support or management processes. The scope must also not include any promotional statements, brands or claims.

When planning the date of certification, the Organization should take into account that all audits in the certification cycle will be carried out at a time when the production of products / provision of services in the scope of certification is carried out, this applies especially to Organizations with seasonal operations.

4. Review / Conclusion of contract with the Client

After accepting the offer, the client sends to PCBC S.A. two copies of the agreement for the certification/re-certification process (a sample agreement is provided at www.pcbc.gov.pl). PCBC S.A. reviews the above agreement for its correctness in terms of formal and substantive. One copy of the agreement, signed on the part of PCBC S.A., is sent back to the Client.

The agreement between PCBC S.A. and the Client may be concluded in an electronic version.

PCBC S.A. shall accept the system documentation necessary for the evaluation in electronic version.

For the sake of information security, it is recommended:

a) upload files offset to .rar .zip or .7z format and properly secured, with the total size of attached files not to exceed 30 MB per message. For attachments, use names, without special characters (e.g.: ?, !,#),
b) use of files in formats: Portable Document Format (.pdf) or Office Open XML File Format (.doc .docx .xls .xlsx .ppt .pptx).

Along with the transferred documentation, the Client should include a list of the transferred documents.

In the case of a large number of documents submitted by the Organization to PCBC S.A., by agreement between PCBC S.A. and the Organization, a storage space for the documentation is determined. The Organization may set aside such space on its own resources or place the documents necessary for evaluation on the PCBC S.A.'s secured FTP server. PCBC S.A. will, for the purposes of the conducted audit, grant the Auditors the rights to view these documents.

5. Information on the composition of the audit team

PCBC S.A., based on the data contained in the application review, appoints a competent audit team to conduct the certification/re-certification/transfer of certification process (hereinafter referred to as the process). A lead auditor and, depending on the needs, technical auditors/technical experts are appointed in each team. Team members are selected from an approved list of auditors/experts, taking into account the competencies needed to achieve the audit objectives, impartiality requirements and the requirements of a given certification program. The audit team as a whole has all the competencies to conduct the process. The composition of the audit team is provided to the Organization at least 7 days in advance before the assessment.

The Organization has the right to apply in writing for a change of individual members of the audit team, e.g. in the event of a conflict of interest or unethical behavior. The application

should be submitted within 5 days of receiving information from PCBC S.A. about the composition of the team. In justified cases, PCBC S.A. will change the members of the proposed composition of the audit team.

Auditors in training, evaluators or observers of the Polish Center for Accreditation may participate in the audit. The participation of the above persons does not financially burden the Organization. The costs are covered by PCBC S.A. In addition, the participation of the above persons is organized in such a way as not to hinder the audit activities of the members of the audit team.

6. Audit of initial certification conducted in two stages

The audit in the Organization begins with an opening meeting. During the opening meeting, among others, the lead auditor confirms the purpose, scope and criteria of the audit, presents the methods of action and audit procedures of PCBC S.A., including information on the confidentiality of the audit team members.

Each temporary location to which the certification Client or certified Organization delivers its products or services is included in the assessment of the certification audit and the audit program.

Remote audit activities normally do not exceed 30% of the planned on-site audit time.

6.1. Stage I of the audit

STAGE I has the following objectives:

a) Review the Client's documented management system information,

b) Assess the Client's site-specific conditions and conduct interviews

with Client personnel to determine readiness for Stage II,

c) Review the Client's status and understanding of the requirements of the standard, particularly with respect to identifying key performance results or significant aspects, processes, objectives and performance of the management system,

d) Obtain necessary information regarding the scope of the management system, including:

- Client's site,
- processes and equipment used,
- levels of established controls (particularly for multi-site Clients),
- applicable legal and regulatory requirements,

e) Review the allocation of resources for Stage II and agree with the Client on the details of Stage II,

f) Focus on planning Stage II by achieving a sufficient understanding of the Client's management system and its operations at the site in the context of the management system standard or other normative document,

g) Assess whether internal audits and management reviews are planned and being conducted, and whether the level of implementation of the management system is management justifies the Client's readiness for the second stage,

When determining the interval between Stage I and Stage II of the audit, PCBC S.A. takes into account the need for the Client to resolve the issues identified during Stage I of the audit.

The interval between Stage 1 and Stage 2 should not be longer than six months. Stage 1 should be repeated if a longer interval is needed.

6.2. Stage II of the audit

The purpose of STAGE II is to assess the implementation, including effectiveness, of the Client's management system.
The second stage should take place at the Client's location(s).
It should include auditing of at least:
a) information and evidence of compliance with all requirements of the relevant management system standard or other normative documents,
b) monitoring, measurement, reporting and review of achievements in relation to key objectives and targets (consistent with expectations in the relevant management system standard or other normative document),
c) the ability of the Client's management system and its operation to meet applicable legal, regulatory and contractual requirements,
d) the Client's operational oversight of processes,
e) internal audits and management reviews,
f) management accountability for the Client's policies.

The 2-stage initial certification audit ends with a closing meeting, at which the lead auditor presents, among other things, conclusions from the audit. The conclusions concern the positive aspects of the assessed system and any comments and non-conformities.

The client has the opportunity to ask questions. Any divergent opinions between the audit team and the client regarding the findings or conclusions from the audit should be discussed and, if possible, resolved. Any unresolved, divergent opinions should be recorded and forwarded to PCBC S.A.

In the event of non-conformities found during the 2-stage initial certification audit, the audit team issues a non-conformity card and explains the procedure for further actions.

Classification of nonconformities:
- minor nonconformity - nonconformity that does not affect the ability of the management system to achieve the intended results;
- major nonconformity - nonconformity that affects the ability of the management system to achieve the intended results;

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

The organization should submit a completed non-conformity card containing a corrective action plan/correction to PCBC S.A. within 5 (15 in the case of EN ISO 13485) working days from the audit date, with the lead auditor notified. The lead auditor reviews the corrections and corrective actions proposed by the organization. Evidence of corrections/corrections for minor non-conformities are assessed during the next audit. Evidence confirming the performance of corrective actions/corrections for major non-conformities should be provided by the organization within 2 months of receiving the non-conformity.

Corrective actions/corrections for major non-conformities identified during audits of all certified management systems are assessed on the basis of an additional audit or evidence that the organization should provide within the above deadline.

An additional audit may be conducted if PCBC S.A. determines the need to verify the effectiveness of the implementation of corrective and corrective actions in the Organization in order to close the nonconformities identified during the audit. An additional audit may be conducted in full or in a limited scope covering only the areas related to nonconformities and actions, the effectiveness of which is to be assessed.

Carrying out an additional audit requires acceptance of the cost estimate for the contract.

A positive assessment of the implementation of corrections/corrective actions by the lead auditor is the basis for applying to PCBC S.A. for a certificate.

Audit report. The audit team delivers an audit report to PCBC S.A., which is subject to verification. Within 30 days of completing all activities, an audit report will be submitted to the Organization in an electronic version approved by PCBC S.A. The Client has the opportunity to present their comments and observations on the entries contained in the report, which they should return within 7 days of receiving the report on the Assessment of Services Provided to the Client received together with the report.

7. Decision on certification

PCBC S.A. makes decisions on: granting/refusing to grant/maintain certification, extending or limiting the scope of certification, extending, suspending or renewing, or withdrawing certification, among others, based on:
- the audit report,
- comments on non-conformities (if any) and, where applicable, corrections and corrective actions undertaken by the Client;
- confirmation of the information contained in the Application for a quote for certification costs,
- confirmation that the audit objectives have been achieved,
- the audit team's recommendation whether to grant certification or not, including all observations,

- positive verification of the audit report,
- any applicable information (e.g. publicly available information).

The organization is informed in writing of the decision taken. The certification document confirming the granting of certification is the PCBC S.A. certificate and the IQNET certificate (optional).

Certification document and/or certificate attachment:

- is signed with a qualified electronic signature by the President of the Management Board
- is issued to the Certified Organization in electronic form.

8. Settlement of costs / Transmission of report / Issuance of certificate

The certificate is issued to the Client after the Client has made payments for a given process based on the invoice sent by PCBC S.A.

The report is the property of PCBC S.A., an electronic copy of the audit report is provided to the Client together with information about the certification decision. The Client has the right to send PCBC S.A. any comments to the report, no later than 7 days from the date of receipt of the report on the Assessment of Services Provided to the Client received together with the report.

The PCBC S.A. and IQNET certificate (optional) is issued for a maximum of three years and cannot be transferred to third parties.

The PCBC S.A. certificate for a given management system is signed by the President of the Management Board. Together with the PCBC S.A. certificate, the IQNET certificate is issued - the International Network of Certification Bodies, associating leading certification bodies from around the world. The IQNET certificate is signed by the President of the Management Board. After successfully completing the certification process, the Client is entitled to receive the PCBC S.A. certified system marks and the IQNET mark by e-mail. The principles for using the certified system marks are specified in a separate document DBC 13.

PCBC S.A. provides the Organization's data on the granted certification, including its status (active, suspended, withdrawn) contained in the issued certificates, to the IAF Database of certified organizations, in accordance with the IAF MD 28 document (applies to certificates covered by PCA accreditation) and the IQNET database of certified organizations (applies to IQNET certificates).

9. Supervision of the system

During the validity period of the certificate, at least 2 surveillance audits are carried out. Surveillance audits should be carried out at least once per calendar year, except in the years in which recertification 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 decision on certification.

Surveillance audits are on-site audits and include, among others:
- internal audits and management reviews;
- review of actions taken in relation to non-conformities identified during the previous audit;
- handling of complaints/claims;
- effectiveness of the management system in terms of achieving the objectives of the certified Client and the intended results of the relevant management system(s);
- development of planned actions aimed at continual improvement;

- continuous operational supervision;
- review of any changes;
- use of the marks and/or any reference to certification.

Other surveillance activities may include:
a) inquiries from the certification body to the certified Client regarding various aspects of the certification;
b) reviewing any statements made by the Client regarding its activities (e.g. promotional materials, website);
c) requests that the certified Client provide documented information (on paper or electronically);
d) other means of monitoring the performance of the certified Client (information may be provided by PCBC S.A.).

As a result of the conducted surveillance audit, the following may occur:
- maintaining the validity of the certificate;
- maintaining the validity of the certificate after a positive assessment of the submitted action plans and/or evidence of the performance of corrective/corrective actions for identified non-conformities through document verification/additional audit;
- suspending/renewing/withdrawing the certificate.

Supervision activities are conducted according to a three-year audit programme in order to systematically monitor the areas and functions covered by the management system.

10. Suspension / revocation of certificate / reduction of scope / extension of scope / audit of transition to new requirements

10.1. Suspension of the certificate validity may occur in the following cases:

- the certified management system of the Organization permanently or to a serious extent does not meet the certification requirements, including the requirements regarding the effectiveness of the management system;
- the Organization does not consent to conducting surveillance audits or audits for recertification with the required frequency specified in the agreement with the Organization;
- at the request of the Organization;
- finding that the Organization has exceeded the rights and obligations specified in the agreement with the Organization;
- finding that the rules regarding the use of the certified system marks have not been met;
- failure to meet financial obligations to PCBC S.A. on time;
- failure by the Organization to fulfill the obligations specified in the agreement with the Organization regarding referring to the certificate and the certified management system;
- an incident in the Organization within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing

Council Directives 90/385/EEC and 93/42/EEC or Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU; (concerns: EN ISO 13485);

The suspension of the validity of the certificate may not exceed six months. During the suspension, the certification is temporarily invalid. In the event of suspension of the Certificate, the Organization refrains from further promoting its certification.

PCBC S.A. resumes suspended certification if the issues that caused the suspension have been resolved by the Organization.

10.2. The certificate may be revoked in the following cases:
- finding that the issues that caused the suspension have not been resolved within the time set by PCBC S.A.;
- finding that the following activities, services or processes covered by the scope of the certificate have been permanently discontinued;
- terminating the agreement with the Organization.

After the certificate is withdrawn, the Organization is obliged to stop referring to the status of a certified Organization and using certificates in all commercial, promotional and advertising activities and documents.

10.3. The scope given in the certificate may be limited in the following cases:
- finding that the issues that caused the limitation of the scope of certification have not been resolved within the time set by PCBC S.A.;
- in order to exclude those parts that do not meet the requirements, when the Organization permanently or to a serious extent does not meet the certification requirements for those parts of the certification scope;
- at the request of the Organization.

The limitation of the scope of certification is confirmed by the issuance of a new certificate with the date of issue from the date of the decision to limit the validity of the previous certificate. In addition, the Organization should return the previous certificate at the request of PCBC S.A.

The suspension / withdrawal / limitation of the scope of the certificate is preceded by an appropriate letter to the Client informing about the need to stop using the certificate and a possible written reminder regarding the return of certification documents (if they were issued in paper form) and with a reminder to stop using the logo of the certified system and the IQNET mark. Suspension may turn into withdrawal of the certificate after the above action is ineffective.

Suspension or revocation of a certificate has the same effect on all annexes issued to it.

10.4. Extension of certification scope/area
The extension of the scope/area of the already granted certification is made at the request of the Organization. The extension requires the submission of an "Application for certification to

PCBC S.A.", based on the review of which the audit activities necessary to make a decision on the extension are determined.
In order to assess the new scope/area of certification, a special audit is carried out or audit activities regarding the reported extension may be carried out in connection with the supervision audit. The above-mentioned extension of the scope includes signing an annex to the contract. The new certificate is issued after the audit and a positive decision of PCBC S.A. The certificate is issued within the validity period of the basic certificate. The certified Organization is obliged to cancel the previous version of the certificate under the principles applicable to it and to use the current version of the certification document.

10.5 Audit of the transition to the new standard requirements
A transition audit is carried out in the event of a new edition of the standard being published and is conducted in accordance with the guidelines contained in announcements issued by PCA and, consequently, by PCBC S.A.
The guidelines include, among others, elements such as:
- transition period – i.e. time to adapt the organization's system to the new edition of the standard;
- self-assessment by the organization regarding readiness to transition to the new edition of the standard,
- information that the transition audit may be carried out as part of a surveillance audit, recertification audit or additional audit,
- the need to add additional audit time for activities related to the transition audit.

As part of the transition audit, the organization is audited for compliance with both the current and new edition of the standard, in order to assess the continuity of the management system.

11. Audit with short notice, or unannounced audit (special audit)
An audit with a short notice period of at least 14 days before the assessment, or an unannounced audit is an audit in response to:
- complaints from interested parties to the certified management system of the organization/client,
- as a result of significant changes introduced in the organization/client,
- as part of further proceedings with a "suspended" organization/client,
- when the products covered by the scope of certification indicate a possible significant deficiency in the quality management system (applies to: EN ISO 13485),
- when PCBC S.A. is aware of significant information related to the safety and operation of the products (applies to: EN ISO 13485),
- when they are required by legal regulations (requirements) resulting from public law or are required by the relevant regulatory body (applies to: EN ISO 13485),
- to justified concerns of the entity regarding the implementation of corrective actions or regarding compliance with the standard and regulatory requirements (applies to: EN ISO 13485). In the event of the above situation, PCBC S.A. shall notify the Client at least 14 days before the assessment of the audit to be conducted with a short notice period that does not require the consent of the Organization. The composition of the audit team is approved by the President of the Management Board.

Unannounced audits are carried out without notice.

11.1. Short-notice or unannounced audits of medical device quality management systems may be required when:

a) occurrence of external factors, such as:

- products covered by the scope of certification indicating a possible significant defect in the quality management system
- significant information known to PCBC S.A. related to the safety and operation of products

b) occurrence of significant changes that have been submitted in accordance with the requirements of the regulations or are known to PCBC S.A. and that may affect the decision regarding the customer's compliance status with the requirements of the regulations

c) when they are required by legal requirements arising from public law or by the relevant regulatory authority

The following are examples of such changes that may be material and relevant to PCBC S.A. when considering whether a short notice or unannounced audit is required, although it is recommended that none of these changes automatically result in a short notice or unannounced audit being conducted:

a) QMS – impact and changes:

- new ownership,
- expansion to include production and/or design oversight,
- new facility, change of location: changes in operations at a location involved in manufacturing activities (e.g., relocation of manufacturing activities to a new location or centralization of design and/or development activities for several manufacturing locations),
- new processes, process changes: significant changes in special processes (e.g., change in production from supplier sterilization to in-house sterilization, or change in sterilization method),
- QM management, personnel: changes in the specific authority of a management representative that affect:

• the effectiveness of the quality management system or regulatory compliance,
• the ability and authority to ensure that only safe and appropriate medical devices are released.

b) Product-related changes:

- new products, categories,
- adding a new product category to the production scope within the quality management system (e.g. adding sterile single-use dialysis kits to the existing scope limited to haemodialysis equipment, or adding magnetic resonance imaging to the existing scope limited to ultrasound equipment).

c) changes related to QMS and products:

- changes in standards, regulations,
- activities related to product safety (post market surveillance, vigilance).

An unannounced audit or an audit with a short notice period may also be necessary when the CAB has justified concerns about the implementation of corrective actions or about compliance with the standard and regulatory requirements.

12. Re-certification

A recertification audit is an audit conducted by PCBC S.A. in the third year, before the certificate expires; it is the basis for issuing a decision to re-grant a certificate for a period of three years.

In the event that corrective/corrective actions resulting from major non-conformities and related to recertification have not been implemented and verified before the certification expires, PCBC S.A. may resume certification within six months, provided that the outstanding recertification actions are completed; otherwise, at least the second stage of the audit must be carried out.

Recertification begins with the Organization submitting an "Application for certification to PCBC S.A.". The condition for maintaining the continuity of the certificate validity is to submit the above-mentioned application at least three months before the certificate expires.

Further proceedings in accordance with points 3, 4, 5 of this document.

The purpose of the recertification audit is to confirm by PCBC S.A. in the Organization:
a) the ongoing compliance and effectiveness of the management system as a whole,
b) the ongoing adequacy and suitability of the management system for the scope of certification,
c) the ongoing fulfillment of all requirements of the applied standard or other normative document.

The recertification audit covers the performance of the management system, taking into account the results of the surveillance audits.

The recertification audit may require a first stage audit, in the event of significant changes to the Client's management system or the context in which the management system operates (e.g. legislative changes) in relation to the previous audit.

The recertification audit is conducted at the Client Organization and includes, among others:
a) the effectiveness of the management system as a whole in light of internal and external changes and its continuing adequacy and suitability for the scope of certification;
b) demonstration of commitment to maintaining the effectiveness and improving the management system in order to improve the overall manner of operation;
c) the effectiveness of the management system in terms of achieving the objectives of the certified Client and the intended results of the relevant management system(s);
d) review of reports from previous surveillance audits;
e) the results of the management system in the last certification cycle.

The decision on granting recertification is made by PCBC S.A. based on:
a) the audit report together with comments on non-conformities and, where applicable, corrections and corrective actions undertaken by the Client;
b) a recommendation whether or not to grant certification together with all conditions and observations;
c) a positive verification of the report by the Report Verifier;
d) any applicable information (e.g. publicly available information);
e) results of the system review during the certification period,
f) any complaints received from those interested in certification.

13. Multi-unit organizations

Multi-site certification may be used in Organizations with multiple production plants or branches that only perform the function of their branches.

Multi-site certification is possible if, among others, the following criteria are met:
a) all locations are legally linked to the headquarters,
b) a uniform management system has been established, implemented and maintained in all locations,
c) central supervision over the management system is exercised by a representative of the highest management appointed by the headquarters,
d) management reviews and internal audits are conducted by the management in all plants and branches.

In the case of a management system operating in multiple branches, PCBC S.A. determines whether sampling is permitted. Sampling of a group of branches is permitted if each branch implements very similar processes/activities. The sample size is selected in accordance with the accreditation requirements in the individual certification programs.

13.1. Additional requirements for multi-site organizations regarding the quality management system for medical devices.

Departments where the design, development and production of medical devices are carried out are not subject to sampling.

14. Complaints / Appeals

In the event of a complaint/appeal filed by the Customer, PCBC S.A. shall proceed in accordance with the procedure available on the website www.pcbc.gov.pl.

15. Protection of customer information and property rights

All PCBC S.A. personnel, both internal and external, are obliged not to disclose any information concerning Clients.

Employees are appropriately trained, instructed and sign an appropriate confidentiality undertaking. Auditors / experts / report verifiers and members of the Committee for Ensuring Impartiality also sign a confidentiality undertaking.

PCBC S.A. in the event of sharing Client data with entities: PCA, IQNET within the scope of its accreditation during the assessments conducted, will, to the extent possible, immediately notify the Client before providing such information.

16. Fees

Fees for certification activities are calculated in accordance with the financial instruction IBC 01.01.

The costs of the certification process include:

a) Fixed fees in the management system certification process (initial fee, fee related to the certification process, certificate issuance, annual fee for participation in the certified Organizations system);
b) Audit examination, at each audit in the cycle (initial certification audit / surveillance audit / recertification audit). The following factors influence the cost of audit examinations, including auditors' working time:
   - employment level (Table No. 1);
   - experience of the Organization in implementing management systems (certificates held);
   - complexity of the Organization and implemented processes, possible exclusions applied, scope of certification, branches held, locations, number of branches covered by the system, geographical dispersion;
   - area of operation of the Organization.

When preparing offers, increasing and decreasing factors are taken into account that may affect both the costs of certification and the planning of auditors' working time.

Examples of factors that increase auditors' working time: complex logistics involving more than one building or location where the activity is carried out, e.g. the need to audit a stand-alone Design Centre, staff speaking more than one language (which necessitates the use of interpreter(s) or precludes the possibility of individual auditors conducting independent activities), large area covered by the audit in relation to the number of staff (e.g. forest), large number of regulations related to the activity (e.g. food, medicine, aviation, nuclear power, etc.), the system includes very complex processes or a relatively large number of unusual activities, activities which require visits to temporary sites to verify activities at the permanent site(s) whose management system is subject to certification.

Examples of factors reducing auditors' working time: Client is not "responsible for design", or other elements of the standard are not in scope (QMS only), low product or process risk, very small site in relation to number of employees (e.g. office complex only), maturity of management system, combined audit of an integrated system consisting of two or more compatible management systems, prior knowledge of Client's management system (e.g. already certified to

another standard by the same CAB), Client's readiness for certification (e.g. Client is already certified or recognized to another third party program), staff includes "off-site" personnel, e.g. salespeople, drivers, service personnel, etc., and it is possible to thoroughly audit their activities against the system in the form of a records review, low complexity activity.

Table No. 1 Guidelines for determining the working time of auditors for evaluation in the certification process (number of audit days).

Relationship between effective number of staff and audit time			
No.	Effective number of staff	Initial certification audit time Stage I + Stage II. (number of audit days)	
		QMS	MDMS
1.	**2.**	**3.**	**4.**
1	1-5	1,5	3
	6-10	2	4
2	11-15	2,5	4,5
	16-25	3	5
3	26-45	4	6
4	46-65	5	7
5	66-85	6	8
6	86-125	7	10
7	126-175	8	11
8	176-275	9	12
9	276-425	10	13
10	426-625	11	14
11	626-875	12	15
12	876-1175	13	16
13	1176-1550	14	17
14	1551-2025	15	18
15	2026-2675	16	19
16	2676-3450	17	20
17	3451-4350	18	21
18	4351-5450	19	22
19	5451-6800	20	23
20	6801-8500	21	24
21	8501-10700	22	25
22	> 10700	According to the trend above	
The values given in rows 1 through 22 define the general timeframe that is the starting point for planning the duration of the audit.			

17. Certification programs

- DBC 17-Program 1 Customer system certification program for compliance with the requirements of the standard EN ISO 9001
- DBC 17-Program 2 Customer system certification program for compliance with the requirements of the standard EN ISO 13485