CERTIFICATION OF MANAGEMENT SYSTEMS ACCORDING TO STANDARDS:

ISO 9001:2015, ISO 13485:2016, ISO 14001:2015, ISO 45001:2018

MANUAL FOR CLIENTS

INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

WWW.ITCZLIN.CZ

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1. INTRODUCTION

Institute for Testing and Certification, Inc. (further only ITC) is an independent testing, calibration, certification and inspectional company worked on evaluation quality and product safety, the certification of management systems and worked on technical standardization.

The subject of this manual is to make easy the preparation of ITC clients' documents, these documents are necessary for the certification of appropriate management system and for better orientation in mentioned questions.

Certification documents issued by the Management System Certification Body at ITC (further only "MSCB"), prove (demonstrate) that the management systems of certified client are established, documented, used and maintained according to particular standards for existing (given) type of management systems. The certificates of management systems are valid for three years and they are valid and adequate from international aspects.

ITC is a member of organization Czech Association for Management systems Certification "CQS", which is a member of international net IQNET. At the same time, it is possible to issue ITC certificate, CQS certificate and so - called IQNET certificate in a certification operation, representing integration to the IQNET. On the basis of the client's requirements it is possible to choose the certification operation only with issue of the ITC certificate, or at the same time the certification operation common to ITC and CQS.

ITC is accredited by the Czech Accreditation Institute for:

- Certification of Quality Management System (according to EN ISO 9001:2015), including Quality Management System of Medical Devices (according to EN ISO 13485:2016)
- Certification of Occupational Health and Safety Management System (ISO 45001:2018)
- Certification of Environmental Management Systems (EN ISO 14001:2015)

The valid accreditation certificates are placed on website www.itczlin.cz and they are available to the clients.

Integrated management systems and audits of these management systems.

Current trend of companies is the implementation of integrated systems and the performance of integrated audits.

The reasons are especially economics, but also organizational-technical, because appropriate systems have many shared ranges and elements. And this is possible to use during implementation and followed certification of management systems.

In the case of client's interest we are able to realize also integrated audit of management systems, e.g . QMS/EMS, QMS/OHSMS, QMS/EMS/OHSMS, etc.

Advantages of integrated audits of management systems:

- less time consuming against the certification of management system, providing separately,
- lower costs on the certification operation.

Geographical areas of Certification Body's Activities

The head of the Management Systems Certification Body is in the Czech Republic, which is the main territory of MSCB activities. Because the certification of management systems belongs to category of voluntary certification, the certification body can realize its services in all territories of the world. In present time MSCB cooperates with auditors in following territories: Brazil, China, India, Israel and Korea.

2. TERMS AND DEFINITIONS

MSCB	Management Systems Certification Body
EMS	Environmental Management System
EN	European standard
IQNET	International network for certification of management systems
ISO	International Organisation for Standardisation
ITC	Institute for Testing and Certification
OHSMS	Occupational Health and Safety Management Systems
QMS	Quality Management System

MSCB Top Management Declaration of Impartiality:

1. The MSCB understands the importance of impartiality during the undertaking of its certification activities by its management system and it controls the conflict of interests and guarantees the impartiality of its activities during certification of the management system.
2. Access to the MSCB services in its accreditation scope is available to all clients. The conditions, which are included in this Manual, exclude an unequal approach of the MSCB to certification services.
3. Every interested party shall be placed to the certification of the management systems on the date of the complete and properly filled application form handing over.
4. The MSCB applies towards the clients consistent non-discriminating requirements, for example the QMS certification according EN ISO 9001 shall not be refused on basis that the supplier is not conformable in fields, to which this standard does not refer (e.g. in environmental management systems).
5. The MSCB provides the access to its services to all applicants. No incorrect financial or other conditions are applied. The accesses are not conditioned on the applicant's size or by membership of any specific association or any group and the certification is not conditioned even on the number of already certified suppliers, except for the QMS certification of other MSCB, which was contrary to the principles (requirements) of the ISO/IEC 17021-1 standard.
6. The CB limits its requirements, assessment and decisions regarding certification only to topics, which specifically concern to the scope of an appropriate certification.
7. The MSCB identifies, analyses and documents the possible conflicts of interests resulting from the undertaking of certification, including any possible conflicts of interests connected with its relationships. The existence of these relationships does not mean in itself necessarily that the MSCB is a MSCB with conflict of interests.
8. MSCB does not offer or provide consultancy to its clients.
9. MSCB behaves and acts in such a way that activities cannot be traded or offered as activity-related activities of an organization providing consultancy. MSCB does not indicate or suggest that certification could be easier, faster or less costly if a specific consulting organization were used.
10. MSCB will not offer and provide internal audits to their certified clients.
11. If MSCB uses for the management system certification personnel who provide consultancy on such a product, or internal audits, a minimum separation shall be of at least 24 months following after end of consultancy or internal audits.

Zlin, September 2018

Ing. Pavel Vanek, m.p.
Head of MSCB

3. CERTIFICATION PROCEDURE

3.1 The basic steps of the certification consist of:

- assessment and registration of client's application to certification
- conclusion of the agreement on performing the certification audit
- appointment and approval of the audit team
- elaboration of the audit plan
- verifying the facts in stages
  - review of client's documentation
  - verification of the reality at the client's site
- elaboration of audit report on certification audit result
- assessment of the audit report by the certification body
- certification decision and issue of the certificate

3.2 Initial certification

Initial certification procedure is in two-stages, i. e. 1st stage certification audit and 2nd stage certification audit. If any significant changes which would impact the management system occur, MSCB consider the need to repeat all or part of stage 1. The results of stage 1 may lead to postponement or cancellation of stage 2.

Application for the certification

If the client is interested in the certification of management system, he/she will fill the Application for certification. After returning of filled application the administrative staff will carry out its registration by delegation of evidence number.

Certification agreement

After review of the application, verification of completeness and relevant filling of missing data the suggestion of the certification agreement is elaborated. The certification agreement is authorized and approved by signatures of both sides.

Preparing for assessment

Preparing for assessment means the appointment of the audit team by the head of MSCB and its approval by the client, reading of the client's documentation. The lead auditor delegates the duties to each member of the team, makes the audit plan, which is sent to the client for approval. Where the client operates shifts, the activities that take place during shift working shall be considered when developing the audit programme and audit plans. The extent of auditing of each shift by the MSCB depends on the processes done on each shift, and the level of control of each shift that is demonstrated by the client.

Assessment

Assessment takes place over these steps:

- opening meeting
- communication during the audit
- collection and verification of information
- identifying and recording findings of audit
- audit conclusions preparation
- closing meeting

Audit report

The lead auditor in cooperation with the members of team elaborates the audit report, which summarizes the results of audit, including expression of conformity or non-conformity of the client's management system with standard requirements, and the recommendation to issue or non-issue of the certificate by the certification body.
In case of findings nonconformities their classification is following:

Major nonconformity: affects the capability of the management system to achieve the intended results. Until the settlement of major nonconformity the certificate shall not be granted in that time, possibly if already is certificate awarded it shall be suspended. If are not remove any major nonconformity **within 6 months after the last day of stage 2**, the certification body shall conduct another stage 2.
Minor nonconformity: does not affect the capability of the management system to achieve the intended results. It shall be accepted the client´s plan for correction and corrective action, its removing shall be done no later than the date outlined in the relevant record about nonconformity. Checking the removing of minor nonconformity shall be done within the next ordinary surveillance (recertification) audit.

Decision about certification

On the basis of record review from the certification audit (Audit report, Non-conformity reports) it is decided on issue (non-issue) of the certificate by the MSCB. MSCB can issue certificate only in case when for all major nonconformities, it has reviewed, accepted and verified the correction and corrective actions and for all minor nonconformities it has reviewed and accepted the client´s plan for correction and corrective action.
If the certification audit passed in good order and the management system is in accordance with the standard's requirements, the MSCB issues the certificate in required language mutations, which is registered below evidence number and it is sent together with the Rules for use of the certificate to the client.

The client has a possibility to use the certification mark of ITC Zlin on the basis of concluded Agreement of Licence and under the conditions mentioned in the Rules for use of the certification mark.

3.3 Procedure for the surveillance and the recetification

Surveillance

The process of the surveillance audit is similar as a certification audit. Validity of the certificate is for three years. During the period of certificate validity, the certification body realizes the surveillance audits within 12 months ± 1 month and 24 months ± 1 month at the client's site from the date of the previous certification decision. The frequency of surveillance audits may be changed if client requests in writtening form and certification body approve it. However, the date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date (the first surveillance audit shall be conducted within 365 days from the certification decision date).

The frequency of surveillance audits may be change to accommodate factors such as seasons or management systems certification of a limited duration (e.g. temporary construction). The change shall be approved between the MSCB and certificated organization.

The MSCB sends the suggestion of surveillance audit agreement to the client for approval. The certification agreement about surveillance is authorized and approved by signatures of both sides.

Surveillance - the preparing of audit and the audit

Preparation of the surveillance audit proceeds in similar way as certification audit. Head of the MSCB nominates the audit team. This audit team is approved by the client. After approval of the audit team the client delivers needed documentation for studying to the lead auditor, and the lead auditor delegates the duties to the members of the team. The audit plan is also sent to the client for approval.

The assessment is carried out at the client's site in the same steps as certification audit.

Surveillance - decision

On the basis of records review from the surveillance audit the MSCB makes the decision of confirmation or suspension of the certificate validity. In both cases the written decision is sent to the client.

3.4 Recertification

A recertification audit shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date.

If the recertification audit is not completed in the full range before to the expiry date of the certificate – validity of certificate is not renewing.

Recertification - the preparing of audit and the audit

Preparation of recertification audit shall be planned and conducted to evaluate the continued fulfilment of all of the requirements of the applicable management system standard. Head of the MSCB nominates the audit team. This audit team is approved by the client. After approval of the audit team the client delivers needed documentation for studying to the lead auditor, and the lead

auditor delegates the duties to the members of the team. The audit plan is also sent to the client for approval.

The assessment is carried out at the client's site in the same steps as certification audit.

Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organization, or the context in which the management system is operating. (In case when these changes occur at any time during the certification cycle, the certification body might need to perform a special audit, which might be a two-stage audit.)

Recertification – decision

On the basis of records review from the recertification audit the certification body makes the decision of renewing or suspension of the certificate validity. The recertification activity considers the performance of the management system over the most recent certification cycle. In both case is sent to client decision in write form.

The re-certification audit is always planned by MSCB to ensure timely renewal of the validity certification:

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

   The validity of the certificate:

   - The date of issue new certificate is the same with the end of validity of current certificate (3 years of the validity of the certificate).
   - The issue date on a new certificate shall be on or after the recertification decision. (certificate may be issued for longer period than is 3 years).

b) If the recertification audit was conducted before the certificate expiry the recertification activities shall be completed till 6 months. In the period from expiry of certificate till recertification decision is client without the validity of certificate. The next certification cycle will be shortened by the period from expiration of certificate until recertification decision it means maximally 6 months.

   The validity of the certificate:

   - The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle (certificate will be issued for shorter period than is 3 years).

c) If the recertification activities are not successfully completed till 6 months after the certificate expiry, the new certificate is not issue and procedures of the certification is ended or:

   1. is needed to repeat stage 2 of audit. The validity of the certificate:
      - The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle (certificate will be issued for shorter period than is 2,5 years).

2. new certification audit is conducted (1 and 2 stage).

d) If the certification audit is not completed prior to the expiry date of the certification the procedures of certification is ended, in case of interested clients for certification shall be conducted new certification audit (1 and 2 stage). The validity of the certificate:
   - 3 years of the validity of the certificate.

During recertification, may be this situation, when certification cycle begins with the certification decision and first surveillance audit shall by conducted till 12 months ± 1 month and second surveillance audit till 24 months ± 1 month from the date of the previous recertification decision (it may be necessary to adjust the frequency of surveillance audits, if client requests in writing and certification body approve it).

4. WHAT IS THE SUBJECT OF EACH AUDIT?

4.1 Minimum scope of the Stage 1 audit covers

- Audit of the client's management system documentation,
- Evaluation of the manufacturing site including specific conditions of the workplace and interview with client's staff concerned readiness to the Stage 2 audit,
- Review of the client's status and his understanding of standard requirements, especially related to identification of the main performance viewpoints, processes, objectives and maintaining of the management system,
- Collection of necessary information relating to the management system scope, processes, and localization of client's workplaces, relevant statutory or legal regulations, and compliance, (e.g. quality, environmental issues, legal aspects of the applicant's activities, related risks etc.), levels of controls established (particularly in case of multisite clients),
- Review of the resources needed for the Stage 2 audit, negotiation with the client aimed to details of the Stage 2 audit,
- Orientation to planning of the Stage 2 audit by a sufficient understanding of the client's management system and activities relating to possible significant aspects,
- Evaluation, if the internal audits and the management review are properly planned (scheduled) and evaluated and if the level of the management system implementation confirms, that the client is ready for the Stage 2 audit.
- Evaluation, if the manner of the management system implementation gives right to conduct Stage 2 audit,
- Further assessment scope depends fully on the lead auditor decision and it is aimed to receiving of additional evidences for evaluation of the above-mentioned steps. However, the scope shall not go beyond the border given by the agreement on Certification.

Addition for the EMS audit:

The audit team evaluates, if:

- System of the EMS includes procedure for identification of the environmental aspects of their activities, products and services
- Is ensured the fulfillment applicable legal requirements and other requirements in relation to its environmental aspects
- Is policy EMS and aim programs to comply with identified environmental aspects,
- Are established and maintained procedures for identification, prevention and reaction to emergency hazard respectively emergency situations that may impact on the environment.

Addition for the OHSMS audit:

The audit team evaluates, if:

- OHSMS system contains an appropriate procedure for hazard identification, risk analysis and risks management
- The legal requirements relevant to the activity of the organization are fulfilled
- OHSMS system is designed by the manner providing for fulfilment of the objectives of the client's OHSMS policy
- The conducted management review has covered an assessment of the suitability, adequacy and efficiency of the OHSMS system
- The OHSMS system contains documentation, relevant communications of the interested parties and reaction to them
- If the client provides services at another organization's premises, the CAB shall verify that the client's OHSMS covers these offsite activities
- Temporary sites, for example, construction sites, shall be covered by the OHSMS of the organization that has control of these sites, irrespective of where they are located.

Addition for the 13485 (Addition to the requirements of MD9 document)

When a certification body has audited a client against a regulatory scheme that includes or goes beyond
the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, providing the certification body may demonstrate that all of the requirements of this document have been complied with.

COSM does not realize this principle.

1st stage audit venue

The 1st stage audits according to ISO 13485 (medical devices class II, III), ISO 14001 and ISO 45001 shall be always performed on site in the client's premises. For other management systems,

the conducting of at least certain parts of the Stage 1 audit in the client's premises is recommended, to perform the above-mentioned tasks successfully.

4.2 Minimum scope of the Stage 2 audit

The Stage 2 audit concerns to the maintaining of the client's management system including its efficiency. The manner of implementation of all requirements according to the appropriate standard shall be checked.

Stage 2 audit shall contain preferably the following items:

- Information and proof of compliance with all requirements of the criteria standard or other normative document related to the assessed management system,
- Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document),
- The client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements,
- Operational control of the client's processes,
- Internal audits and management review,
- Management responsibility for the partial client's policies,
- Links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions,
- Other range of assessment is fully in competence of the lead auditor and it is always directed to the obtaining of sufficient evidence to the evaluation of previous points. The range of auditing given by the lead auditor shall not exceed the frame of the certification contract clause.

Addition for the EMS audit:

The audit team shall focus to:

- Processes of identifying and managing environmental aspects of its activities, products and services
- Processes for securing and evaluating compliance with legal and other requirements
- Objectives and target programs are set up linked to significant environmental aspects
- Emergency preparedness and response to emergency situation
- Managing related to environmental aspects
- Monitoring and measuring key characteristics of operation which may have environmental impact.

Addition for the OHSMS audit:

The audit team shall focus to:

- Processes of the OHSMS hazards identification, risk assessment and risk management,
- The procedures for the securing and evaluation of compliance to legal requirements and other relevant specifications,
- Establishment of the OHSMS objectives and programs and fulfilment of them,
- The operational management of the organization,
- Performance monitoring, measuring, reporting and reviewing against specified OHSMS objectives and targets
- Incident review, nonconformities, corrective and preventive actions,
- The links between OHSMS policy and all articles of the OHSMS system and co-operative ability of them.
- If the client provides services at another organization's premises, the CAB shall verify that the client's OHSMS covers these offsite activities
- Temporary sites, for example, construction sites, shall be covered by the OHSMS of the organization that has control of these sites, irrespective of where they are located,
- Ensure that the externally provided functions or processes do not adversely affect the effectiveness
  of the OHSMS, including the organization's ability to control its OHS risks and commitments to comply with legal requirements.

Audit venue

The Stage 2 audits shall be always performed on site in the client's premises.

During the certification of management system according to ISO 13485 each workplace, where the development and/or production of medical devices are carried out, which are included into the certified management system.

4.3 Minimum Scope of the Surveillance Audit

- Internal audits and review of the management,
- Review of the actions undertaken for dealing with nonconformities identified during the previous audit,
- Dealing with complaints,
- Efficiency of the management system with regard to objectives achievement of the certified client, and the intended results of the respective management systems,
- Procedure of planned activities with objective of permanent improvement,
- Permanent operational management,
- Review of all changes,
- Usage of marks and/or other references to certification.
- Assessment the findings recorded in the Audit Report from previous audit (including places for improvement).

Addition for OHSMS

The team of auditors assess if:

- ensure that the externally provided functions or processes do not adversely affect the effectiveness
  of the OHSMS, including the organization's ability to control its OHS risks and commitments to comply with legal requirements.

Audit venue

The surveillance audit usually take place on site at the client's premises. It is possible in agreement with the client and the evaluation of the suitability of the use of information communication technology, a remote assessment may be performed to the extent specified in the audit plan.

During the certification of management system according to ISO 13485 each workplace, where the development and/or production of medical devices are carried out, which are included into the certified management system.

4.4 Minimum Scope of the Recertification Audit

- Dealing with the effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;
- Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;
- The effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s).

Addition for OHSMS

The team of auditors assess if:

- ensure that the externally provided functions or processes do not adversely affect the effectiveness
  of the OHSMS, including the organization's ability to control its OHS risks and commitments to comply with legal requirements.

Audit venue

Recertification audit usually take place on site at the client's premises. It is possible in agreement with the client and the evaluation of the suitability of the use of information communication technology, a remote assessment may be performed to the extent specified in the audit plan.

5. EXTENSION (CHANGE) OF THE CERTIFICATION SCOPE

The MSCB on the basis of an application for the extension (change) of the scope of already granted certification conducts a review of the application and defines all the audit activities necessary for the decision whether the extension (change) can be granted to the applicant or not. This can be conducted in connection with a surveillance audit or by the conducting of special audit. The principles and procedures of the audit are the same as the procedure of audit.

6. SUSPENSION AND WITHDRAWAL OF THE CERTIFICATE

The MSCB suspends certification (certificate) in cases when:

- the certified client's management system permanently or seriously fails during the fulfilment of certification requirements, including requirements for the effectiveness of management system,
- the certified client does not allow the performing of surveillance audits or re-certification in required frequency,
- the certified client has asked for suspension.

During the suspension, the certification of the client's management system is temporarily invalid. The MSCB restores the suspended certification if the issue that has resulted in the suspension has been resolved.

The suspension date of the certificate is possible maximally for 6 calendar months. There is an arrangement, that the client desists from any other promotion with reference to the certification in case of suspension, between MSCB and its clients in the agreement on certification.

The MSCB puts the information about the status of certification suspension publicly accessible in the database of certificates located at www.itczlin.cz and takes such actions as it considers appropriate.

Provided that in the time determined by the MSCB the problems, which are the reason for suspension, are not be solved, this fact leads to withdrawal of the certificate or to reducing of the certification scope.

The MSCB reduces the scope of the client's certification in the event that the client continuously or seriously does not fulfil the certification requirements for specific parts of the scope of the certification. All such reductions shall be in conformity with requirements of the standard used for the certification.

The reduction of the certification scope is providing by the regular surveillance audit, the re-certification audit or by the extra-ordinary surveillance audit. And then by issuing of the changed certificate with the reduced certification scope.

The MSCB **withdraws the certificate** in the following cases:

- On the client's request.
- The client has not undergone the surveillance audit in the specified time interval or when the client did not provide the necessary co-operation to perform the audit
- The client did not apply the corrective actions in the specified time interval in cases, where the certificate had been already withdrawn.

The withdrawal of the certificate is provided by the head of the MSCB by the written decision delivered to the certificate holder by the registered letter. The relevant steps expected by the MSCB to be fulfilled by the certificate holder are specified in the Agreement on Certification and Licence Agreement (if the later has been concluded) and by the Rules for using Certificate and Certification Mark.

The MSCB has prepared and has made available a publicly accessible database of certificates located on www.itczlin.cz, where the questioner (anybody) can find out the status of certification of a client's management system – i.e. whether the certification is valid, suspended, withdrawn or reduced.

7. MINIMAL INFORMATION CONTENT OF CERTIFICATION DOCUMENTS

The certification documents shall detail:

- The name and geographical location of each client whose management system is certified (or geographical location of the headquarters and of all premises relevant to the terms of certification in more than one location),
- The effective date of granting, expanding or reducting the scope of certification, or renewing certification, COSM fulfilment the requirements for certification documents that the date of the effective of documents shall not be before the date of the relevant certification decision. The head of the certification department is responsible for the compliance of this procedure. The certification body may keep the original certification date on the certificate when a certificate lapses for a period of time provide that the current certification cycle start and expiry

date are clearly indicated. The latest certification cycle expiry date be indicated along with the date of recerfication audit.

- The expiry date or recertification due date consistent with the recertification cycle,
- A unique identification code,
- The standard, and/or a document according to another standard, utilized for the audit of the certified client (including the number of issue and of its revision),
- Scope of certification with respect to the type of activities, products and services process etc. in a manner corresponding with each workplace;
- Name, address and certification mark of a CB; other marks (e.g. symbol of accreditation, client´s logo) may be used providing that they are not misleading and that they are unambiguous,
- All further information required by the standard or by any other standard document utilized for certification,
- In the event of issuance of any revised certification documents a means for distinguishing revised documents from all previous obsolete documents.

8. NOTICE OF CHANGES BY A CERTIFIED CLIENT

The MSCB has a legally enforceable arrangement for guaranteeing that a certified client will inform the MSCB without delay about such matters as could influence the competence of the management system to continuously fulfil the requirements of the standards utilised for certification.

This includes, for example, changes referring to:

- Legal, business, organisational status or ownership,
- Organisation and top management (e.g. key top managers, employees responsible for decision-making or technical experts and specialists),
- Contact addresses for and contacts at individual workplaces,
- Scope of operations under the certified management system
- Substantial changes to management systems and processes.

Addition for OHSMS

- informs the Certification Body, without delay, of the occurrence of a serious incident or breach of regulation necessitating the involvement of the competent regulatory authority

Addition for ISO 13485

- the certificate holder undertakes to continuously inform ITC in writing about all changes that have an impact on the ability and authority of the certificate holder to ensure that only safe and effective medical devices are placed on market, especially about reporting adverse events and advisory notices (Medical Devices Vigilance System) and recall of the medical devices from the market.

The MSCB on the base of this information sets and implements appropriate measure.

9. APPEALS, OBJECTIONS, COMPLAINTS

The MSCB is obliged to deal with appeals, objections, complaints and disputes, submitted to the MSCB by suppliers or by other parties.

MSCB deals with written appeals, objections, complaints and disputes. They are received and registered.
The complainant can be every individual or corporation, which expresses its opinion of dissatisfaction to our provided services or to procedure realized within the ITC management system.

Anonymous complaints are not settled – they are only registered.

Appeal	The appeal is a request from the ITC client to re-examine the background and conditions of any decision made by the certification body for management systems and is not an explicit expression of dissatisfaction with the outcome of the service process. As a rule, appeals include additional information or a more detailed explanation of the person or organization concerned about certain facts in previously submitted documents.
Complaint	A complaint is an explicit and addressed expression of a complaint or dissatisfaction regarding the results or parameters with the certification body for management systems or the process of the service itself, where the complainant expects the verification, response, and corrective action of the subject matter of the complaint. Anonymous complaint is a complaint to which the complainant can not be identified. Anonymous complaints are recorded, but are not handled.
Complainant	Person, organization, or a representative who applying the complaint. The complainant may also be a person who did not provide the service or the product that is the subject of a complaint by ITC. The complainant may also be an internal employees, ie a manager or employee employed by the ITC.
Objection	The objection is considered to be a written statement by the client about the stages of the certification process that ITC as a Certification Service Provider is required to inform the client in advance in accordance with applicable regulations, standards and internal procedures. The objection relates to the circumstances of the process that has not yet occurred.
Submitter	Person, organization or its representative submitting a complaint / objection / appeal.

General procedure:

1. Any ITC personnel, who informs first line supervisor of the complaint, can receive each appeal, objections, complaint from complainant. This supervisor then informs the Manager of appropriate division. Manager of division hands over every complaint to the ITC General Director.
2. The General Director decides about complaint registration and at the same time establishes the responsible personnel for its solution (further only "Complaint solver").
3. The complaint is registered and handed over to the appropriate complaint solver to execution. At the same time the complainant is informed of complaint acceptance (by post, by e-mail).
4. The complaint solver shall reply to complaint within 10 days from its registration.
5. The complainant shall lay claim in written form, if the requirement for financial performance ensues from complaint solution. It is necessary to count and submit the real spent expenses by the complainant.
6. The official standpoint will be accepted to each complaint. The complainant will be informed with this standpoint in written.
7. All information, identified to complainant during complaint solution, is available exclusively for purposes of working with complaint within ITC and this information is confidential, except in information, where the complainant has agreed faithfully (and demonstrably) with publication of the information.
8. Submission, investigation and decision on complaints does not result in any discriminatory actions against the complainant.

All external complaints are received in written form at the address:

Institut pro testování a certifikaci, a.s.	or by e-mail:	director@itczlin.cz;
třída Tomáše Bati 299		iskrivankova@itczlin.cz;
763 02 Zlin		jsimkova@itczlin.cz

In the head of letter or e-mail, please, mentioned the subject "APPEAL", "OBJECTION" or "COMPLAINT" for better identification.

10. CONTACTS

Head of the certification body (MSCB) and Director of Certification Division

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Deputy of the head of MSCB and Deputy of Director of Certification Division

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The head of the certification department, Deputy of the head of MSCB

Ing. Jaroslav Rapant

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11. CONCLUSION

The subject of this manual for the clients of management system certifications is to acquaint the clients with the activity of MSCB and by this way make easy the orientation in questions of the certification procedure to the clients.

12. LIST OF THE APPLICATIONS FOR THE CERTIFICATION OF THE MANAGEMENT SYSTEMS

The Application for the Quality Management System according to: EN ISO EN ISO 9001:2015, EN ISO 13485:2016, EN ISO 14001:2015, ISO 45001:2018.

Above-mention applications are available on www.itczlin.cz .