



Manual for ITC Clients

Certification of management systems according to international standards

**ISO 9001:2008, , ISO 13485:2003, ISO 14001:2004
BS OHSAS 18001:2007, ISO 22000:2005,
and HACCP according to the Czech Republic's Ministry of
Agriculture Bulletin No. 1/2001, part 1. – 4.**

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1. Introduction

Institute for Testing and Certification, Inc. (further only ITC) is independent testing, calibration, certification, consulting and inspectional company worked on evaluation quality and safeness products, certification management system and environmental management and worked on technical standardization.

The subject of this manual is to make easy preparation of documents from ITC clients, these documents are necessary for certification particular management systems and better orientation in mentioned problems.

Certification documents issued by Management System Certification Body No. 3002 at ITC (further only "MSCB"), argue 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 year and they are valid and adequate from international aspects.

ITC is a member of organization Czech Association for Quality 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 process, representing integration to the IQNET. On the basis of client's requirements it is possible to choose certification process only with issue of certificate ITC, or at the same time certification process common to ITC and CQS.

ITC is accredited by Czech Accreditation Institute for:

- Certification of Quality Management System (according to EN ISO 9001:2008 and EN ISO 9001:2000), including Quality Management System of Medical Devices (according to EN ISO 13485:2003) and Certification of Critical Control Points System (HACCP)
- Certification of Occupational Health and Safety Management System (according to OHSAS 18001:1999 and BS OHSAS 18001:2007)
- Certification of Food Safety Management Systems (according to EN ISO 22000:2005)
- Certification of Environmental Management Systems (according to EN ISO 14001:2004)

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 construction integrated systems and performance of integrated audits.

The reasons are especially economics, but also organizational-technical, reasons, because individual systems have many united ranges and elements. And this is possible to use at 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/OHSAS, QMS/EMS/OHSAS, etc.

Advantages of integrated audits of management systems:

- lower time heftiness against certification of management system, examining separately
- lower costs on certification process



Geographical areas of Certification Body's Activities

The head of 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 realized its services in all territories of the world. In present time MSCB cooperates with auditors in following territories: Brazil, India, Israel, Korea, Pakistan, Poland and Turkey.



MSCB Top Management Declaration of Impartiality:

The MSCB-3002 has a commitment to the impartiality of its top management, in regard to its activities in the certification of management systems.

1. The CB recognises the importance of impartiality during the undertaking of its certification activities by its management system and it controls conflict of interests and guarantees the impartiality of its activities during certification of the management system.
2. Access to the MSCB-3002 services in its accreditation scope is available to all customers/clients. The conditions, which are included in this QM, exclude an unequal approach of the MSCB-3002 to certification services.
3. Every interested party must be subsumed to certification of the management systems on the date of handing over of the complete and properly filled application form.
4. The MSCB-3002 employs towards the customers consistent non-discriminating requirements, for example the QMS certification according ČSN EN ISO 9001 must 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-3002 facilitates access to its services to all applicants. No improper financial or other conditions are employed. Access is not conditional on the size of the applicant entity or by membership of any specific association or group and certification is not conditional even on the number of already certified suppliers, except for QMS certification of other MSCB-3002, which was contrary to the principles (requirements) of the ISO 17021 standard.
6. The CB limits its requirements, assessment and decisions regarding certification only to topics, which specifically concern the scope of a particular certification.
7. The MSCB-3002 identifies, analyses and documents 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 in itself necessarily mean that the MSCB-3002 is a MSCB-3002 with conflict of interests.

Zlín, August 2009

Ing. Pavel Vanek
in own hand
the Head of MSCB



2. Certification procedure (process)

The basic steps of the certification process consists of:

- assessment and registration of client's application to certification
- conclusion of the agreement on performing the certification audit
- appointment of the audit team
- elaboration of the audit plan
 - a) review of client's documentation
 - b) verification the reality at the client's site
- elaboration audit report on certification audit result
- assessment of the audit report by the certification body
- issue of the certificate

Certification process is two-stages, i. e. 1st stage certification audit and 2nd stage certification audit.

APPLICATION FOR THE CERTIFICATION

If the customer is interested in certification of management system, he/she will fill in the Application for certification. After returning filled application administrative staff will carry out its registration by delegation of evidence number. After review of the application, verification of completeness and relevant filling of missing data the suggestion of certification agreement is elaborated. 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 customer for approval.

ASSESSMENT

Assessment passes over these steps:

- opening meeting
- communication during the audit
- collection and verification of information
- 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 recommendation to issue or non-issue of the certificate by certification body.

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 certification body. If the certification audit passed in good order and the management system is in accordance with the standard's requirements, the



certification body issues the certificate in required language mutations, which is registered below evidence number and it is sent complete with the Rules for use of the certificate to the customer. The customer has a possibility to use the certification mark of ITC Zlín on the basis of concluded Agreement of Licence under the conditions mentioned in the Rules for use of the certification mark.

PROCEDURE FOR THE SURVEILLANCE AND THE FOLLOW-UP ASSESSMENT

Surveillance - the agreement

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 and 24 months at the customer's site. The Certification body sends the suggestion of surveillance audit agreement to the customer for approval. Approved and authorized agreement is sent to customer for sign-up.

Surveillance - the preparing of audit and the audit

Preparation of the surveillance audit proceeds in similar way. Head of the certification department nominates the audit team. This audit team is approved by the customer. After approval of the audit team the customer 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 customer for approval. The assessment is proceeded at client's site as the certification audit.

Surveillance - decision

On the basis of record review from the surveillance audit the certification body makes the decision of confirmation or suspension of the certificate validity. In both cases the written decision is sent to the customer.

3. What is the subject of each audit?

3.1 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 employees concerned readiness to Stage 2 audit
- Review of the customer'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 customer's workplaces, relevant statutory or legal regulations, and compliance, e.g. quality, environmental issues, legal aspects of the applicant's activities, related risks etc.)
- 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 management reviews are properly 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.

Supplement for the OHSAS audit:

The audit team evaluates, if:

- OHSAS 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
- OHSAS system is designed by the manner providing for fulfillment of the objectives of the client's OHSAS policy
- The conducted management review has covered an assessment of the suitability, adequacy and efficiency of the OHSAS system
- The OHSAS system contains documentation, relevant communications of the interested parties and reaction to them

Supplement for the ISO 22000 audit:

- Availability of the relevant authorizations (approval of the operation process, obligatory analysis etc.) and their compliance to legal requirements
- Identification of PNP, suitable for client's enterprise
- Review, if the FSMS contains appropriate processes and methods of identification of hazards related to food safety and subsequent selection and categorization of the controlling measures (or combinations of them)
- Implementation of the legislation related to food safety for relevant sector(s) of the organization
- Review, if the FSMS is designed by the manner providing for fulfillment of the food safety policy in the organization
- Adjustment of the FSMS implementation and possibility to conduct Stage 2 audit
- Validation, verification and improvement programs compliant to the FSMS standard requirements

1st stage Audit venue

The EMS and OHSAS Stage 1 audits shall be always conducted 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.

3.2 Minimum scope of the Stage 2 audit

The Stage 2 audit concerns 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 and performance as regards legal compliance,



- Operational control of the client's processes,
- Internal auditing and management review,
- Management responsibility for the 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.

Supplement for the OHSAS audit:

The audit team shall focus to:

- Processes of the OHSAS hazards identification, risk assessment and risk management,
- The procedures for the securing and evaluation of compliance to legal requirements and other relevant specifications,
- Estimation of the OHSAS targets and programs and fulfilling of them,
- The operational management of the organization,
- Performance monitoring, measuring, reporting and reviewing against specified OHSAS objectives and targets
- Incident review, nonconformities, corrective and preventive actions,
- Internal audits and management review conducting,
- Management responsibility for the OHSAS policy,
- The links between OHSAS policy and all elements of the OHSAS system and co-operative ability of them.

Audit venue

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

3.3 Minimum Scope of the Surveillance Audit

- Internal audits and review of the management,
- Review of the measures undertaken for dealing with nonconformities identified during the previous audit,
- Dealing with complaints,
- Performance of the management system with regard to achievement of goals by the certified customer,
- Progress of scheduled activities whose goal is sustainable improvement,
- Sustainable operations management,
- Review of all changes,
- Usage of marks and/or other references to certification.

Surveillance audits must be undertaken at least once per calendar year. The date of the first surveillance audit following after the initial certification should not be set for longer than 12 months from the last day of the Stage 2 audit (i.e. the first surveillance audit must be started within 365 days from the last day – in site – of the Stage 2 of the certification audit).

Audit venue

The surveillance audit shall be always conducted on site in the client's premises.

4. Extension (change) to the certification scope



The MSCB-3002 on the basis of an application for the extension 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 can be granted to the applicant or not. This can be conducted in connection with a surveillance audit or by the conducting of an irregular audit. The principles and procedures of the audit are the same as the procedure of audit.

5. Suspension and withdrawal of the certificate

The MSCB-3002 **suspends certification** (certificate) in cases when:

- the certified customer's management system permanently or seriously fails during the fulfilment of certification requirement, including requirements of effectiveness of management systems,
- the certified customer does not allow conducting of surveillance audits or audits or re-certification in required frequency (in determined term – i.e. at the latest after the expiration of the following calendar month, which was defined by the MSCB-3002 in part B of Audit Report, or the latest after expiration of three calendar months in event of serious reasons on customer's side which were substantiated in written form and the customer simultaneously requested in written form the postponing of the surveillance audit),
- The certified customer voluntarily asked for suspension.

During the suspension the certification of the customer's management system is temporarily invalid. The MSCB-3002 has (in contract about certification and in Rules for Using of Certificate and Certification Mark) enforceable arrangements with its customers providing that in the event of suspension the customer must abstain from any further promotion with reference to certification.

The CB makes the information about the status of suspension of certification publicly accessible in a database of certificates located at www.itczlin.cz and takes such measures as it considers appropriate.

Provided that in the time determined by the CB the problems, which represent the reason for suspension are not be solved, this fact will lead to withdrawal of the certificate or to restriction of the scope of certification.

The MSCB-3002 **restricts the scope of the customer's certification** in the event that the customer continuously or seriously does not fulfil the certification requirements for specific parts of the scope of the certification. All such restrictions must be in conformity with requirements of the standard utilised for the certification. The regular surveillance audit and following issue of changed certificate with restricted certification scope provides the restriction of the certification scope.

The MSCB-3002 **withdraws the certificate** in the following cases:

- On the client's request.
- The client did not undergo the surveillance audit in the specified time interval (beginning of the first surveillance audit not later than 365 days after the last day of the Stage 2 audit).
- The client did not apply the corrective measures in the specified time interval in cases, where the certificate had been already withdrawn.

The withdrawal conducts the manager 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.

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



6. Appeals, objections, complaints

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

MSCB deals with written appeals, complaints and disputes (further only "complaint"). 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 process realized within the ITC management system.

Anonymous complaints are not settled – they are only registered.

General procedure:

1. Any ITC personnel, who informs first line supervisor of the complaint, can receive all complaints 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 complainant.
6. The official standpoint will be accepted to each complaint. The complainant will be informed in written with this standpoint.
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.

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

Institute for Testing and Certification, Inc.
tr. T. Bati 299
764 21 Zlín

or by e-mail: director@itczlin.cz;
iskrivankova@itczlin.cz;
jsimkova@itczlin.cz

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



7. Contacts

Head of the certification body (MSCB)

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Representative of the head of MSCB, the head of the certification department

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8. Conclusion

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

9. List of the Applications for the certification of the management systems

1. The Application for the Quality Management System according to EN ISO 9001:2008
2. The Application for the Quality Management System certification according to EN ISO 13485:2003
3. The Application for the Environmental Management System certification according to EN ISO 14001:2004
4. The Application for the Occupational Health and Safety Management System certification according to BS OHSAS 18001:2007
5. The Application for the Food Safety Management System certification according to EN ISO 22000:2005

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