

LL-C (Certification)[®]



CERTIFICATION PROCEDURE
1) MANAGEMENT SYSTEMS
2) PRUDUCTS, PROCESSES AND SERVICES

(Rule-03)



Revision No. 42 from 16.06.2022 Published: Ing. Lukáš Holub, Ph.D.

Contents

I.	Supporting Statement	3
II.	Objectives and Scope	4
III.	Definitions and Abbreviations	5
IV.	A) Selection and Use of Certification Standard	5
IV.	B) Selection and Use of Certification Scheme.....	6
V.	Certification processes	9
	Diagram certifikačního procesu – certifikace výrobku/procesu	18
	(I-B, I-C) – posuzování systému řízení, správné výrobní praxe,	18
	Diagram certifikačního procesu – certifikace výrobku/procesu	19
	(I-B, I-C) – zkoušení vykonané CO	19
VI.	Suspension or withdrawal of certificate	24
VII.	Transfer of certification	25
VIII.	Responsibility of Certification Body	26
IX.	Responsibility of Certification Holder	28
	A) Certification of management systems.....	28
	B) Certification of products	29
X.	Application of Certification Rules modifications	30
XI.	Financing and certification fees	30
XII.	Complaints and Appeals Procedure	30
XII.	Commitment information	31
	List revisions and motivations	32

I. Supporting Statement

Certification body LL-C (Certification) Czech Republic a.s. ("LL-C") provides certification services against national standards on various Management Systems like Quality Management Systems as per ISO 9001:2015, ISO 9001 in connection with NV 333/2011 Environmental Management Systems as per ISO 14001:2015, Occupational Health & Safety Management Systems as per ISO 45001, Information Security Management Systems as per ISO/IEC 27001, in management of Critical Control Points in the Food Industry with requirements of Food Safety Management Systems as per ISO 22000 and FSSC 22000 scheme) with the requirements of the HACCP and the and IT Service Management Systems as per ISO 20000-1, both in production and services companies In Energy Management (ISO 50001) and furthermore, under the accreditation of ANSI / ANAB (U.S.A.) Certification according to ISO 9001, ISO 22301 and ISO 28000 standards.

LL-C provides certification of products according to EN ISO 3834, EN 15085-2 (:2007 CL1 až CL4, :2020 CL1 až CL3), EN 17660-1, EN 17660-2, EN 14554-1, EN 14554-2 and ISO 22716 and GMP+ FSA scheme and e-IDAS, in the scope of its accreditation and in conformity with ISO/IEC 17065, EA-6/02 and valid Guidelines for accreditation.

LL-C provides certification of products (Construction products REG EU 305/2011, construction products according to (NV No. 163/2002 Coll. as amended by NV No. 312/2005 Coll. and No. 215/2016 Coll.), Medical Devices and Machinery Devices), Pressure equipment (further only PED), simple pressure vessels (SPVD), and machinery in the scope of its accreditation and in conformity with ISO/IEC 17065.

The legal status of the organization is a joint-stock company registered under file number B 22724 kept at the Municipal Court in Prague. The company was established as a subsidiary in the Czech Republic to its service closer to the needs of local candidates on the certification and understand the conditions and needs of the parties that the results of certification activities using or relying on them. The company is registered with the Municipal Court in Prague. The company operates in the EU and beyond.

Certification services are available to all candidates who adopt the rules laid down in this Directive and demand for the certification.

A proclaimed policy of the LL-C and its management is to provide certification of Management Systems and Products only within its own certification system ensuring impartiality, confidentiality and independence for the certified client. The policies specified for LL-C personnel regarding knowledge, skills and relevant experience are equally applicable for external auditors/evaluators/technical experts. At present, LL-C does not outsource any of Management System Certification Activities.

Auditors, evaluators or technical experts, involved in the certification process are required to carry out its functions to the exclusion of any influence from third parties. External auditors, evaluators and experts are bound by strict rules of impartiality and

LL-C (Certification)[®]

independence of the certification system. All carry out their activity based on the following principles:

- Maintaining the same access to all certified operators, excluding any discrimination against organizations or individuals
- Exclusion from participation in the audit and the decision on granting a certificate for an individual client the personnel which is personally involved in consulting activities in the management systems (above mentioned standards). So, the impartiality and independence of the assessment for a particular client has been secured.
- Exclusion from participation in evaluation activities and in decision on granting a certificate for an individual client the personnel whose activities might be considered as consulting, support by designing, operation with products, creation relevant inspection processes which violate the obligation of impartiality
- Strict separation of audit / expert opinion and the decision on certification
- Strict separation of evaluation/assessment of conformity and decision on certification
- Strict respect of confidentiality of all personnel involved in the certification process.

LL-C activities are based on following policies and principles:

- philosophy to promote confidence in certification as an effective instrument for improving the quality of products and services and more careful approach to the environment and other risks
- improving the security of information systems
- ensuring the highest possible level of integration during assessment of management systems according to various established standards and regulations
- ensuring the territorial and term availability of auditors and evaluators
- ensuring personnel with relevant experience and competence - auditors and evaluators regarding applicable field, audit or evaluation experience and no less ethical behaviour and empathy
- strict respect of confidentiality
- preference of effectiveness of precautions to formality of compliance with the requirements of standards
- using the most modern techniques for the testing and adoption of such organizational measures to prevent conflicts of interest and challenge test results.

II. Objectives and Scope

Objectives

The present Rule defines:

- A) the procedure to be used for Certification of Management Systems. It explains the principle of the certification process and procedures which are relevant for organizations interested in certification. Instruction is based on the requirements of ISO 17021-1:2015, current MPA, ČSN EN ISO 19011:2012, ČSN EN ISO 19011:2021 and requirements of private schemes (FSSC 22000, GMP+ FSA, IFS)
- B) the procedure to be used for Certification of Products. It explains the principle of the certification process and procedures which are relevant for organizations interested in certification. Instruction is based on the requirements of ISO/IEC 17065 and requirements of private schemes (IFS, GMP+ FSA).



LL-C (Certification)[®]

Scope

This instruction applies to Certification of Management Systems of organizations active in the production, services in non-state or government sector in the areas of scope of accreditation according to LL-C.

This instruction applies to Certification of Products of organizations active in the production of products – devices in the scope of accreditation according to LL-C.

The regulations or standards specific to a particular field that are not here well appointed, the provisions of this Rule will be adequately applied in relation to such regulations or standards. Any non-conformities or deviations will be presented to a client case by case, according to specific requirements.

III. Definitions and Abbreviations

The present Rule contains definitions from:

ISO 17021-1:2015 - General requirements for certification bodies for Management System Certification (including current MPA, IAF MD, etc.)

EN ISO 19011 - Guidelines for Auditing of Management Systems

EN ISO/IEC 17065 - General Requirements For Bodies Operating Product Certification Systems

Used abbreviations:

- CB – Certification Body
- CBP – CB for Product Certification
- HCB – Head of CB
- DHCB – Deputy Head of CB
- QM – Quality Manager
- E – Evaluator which provides Assessment of Conformity
- LE – Lead Evaluator
- DM – Decision Maker on Certification
- TE – Technical Expert

IV. A) Selection and Use of Certification Standard

Quality Management Systems

For certification of quality management systems is used standard ISO 9001 current version. Out of this standard, quality management system must meet the expectations of the relevant field and customers.

SJ-PK system

For certification, the quality system in the field of roads (SJ-PK) in order to increase the quality of work in construction, repair and maintenance of roads is regulated by the Ministry of Transport, which develops and complements SJ-PK for quality development and requirements for SJ-PK and technical conditions defining the requirements for ensuring the quality of supplies, services or documents to a minimum level by the criteria for the technical qualification of the tenderer for the supply, service or works contract.



LL-C (Certification)[®]

The certification process is applied in accordance with the system standards ČSN EN ISO, legal regulations. SJ -PK applies to works and activities at PK listed in individual parts of MP for areas according to Article 3 of SJPk.

The methodological instruction SJ-PK, technical standards, regulations, TKP (technical quality conditions) and TP (technical conditions) according to the current valid version at www.pjpk.cz, which is maintained by the Ministry of Transport, are used for certification.

Environmental Management Systems

For certification of environmental management systems is used standard ISO 14001 current version. Out of this standard, management system must meet the expectations of the relevant field and customers.

Information Security Management Systems

For certification of information security management systems is used standard ISO 27001. Out of this standard, management system must meet the expectations of the relevant field and customers. In ICT sector is more and more often used **IT Service Management Systems** as per ISO 20000-1 which contains elements of management of outsourcing of IT services, quality management of ICT services and information security management systems.

Management of Critical Control Points

in the Food Industry is certified in accordance to HACCP prescription (FAO/WHO Codex Alimentarius). Out of this standard, management system must meet the expectations of the relevant field and customers. On this system are built more comprehensive **Food Safety Management Systems** (ISO 22000 and FSSC 22000, GMP+ FSA) which that more integrated system of feedback and process management, and compatibility with the quality.

Occupational Health & Safety Management Systems OHSAS 18001/ISO 45001

For certification of Occupational Health & Safety management systems is used standard ISO 45001. Out of this standard, management system must meet the expectations of the relevant field and customers.

Energy management

This system analyses energy sources, basal consumption and plans to influence it in terms of savings in both the application of organizational and technological measures. The benefit of certification, which in some jurisdictions is also compliance with legislation, should also be energy savings. The criterion standard is ISO 50001.

Other management systems

For using other standards, the requirements can be completed by additional requirements of relevant accreditation or contractual entity. These specific requirements will be provided to interested parties case by case.

IV. B) Selection and Use of Certification Scheme

Product/Processes as per EN ISO 3834-2/3/4, EN 1090-2/3, EN 15085-2 (:2007 CL1 až CL4, :2020 CL1 až CL3), EN 17660-1, EN 17660-2, EN 14554-1, EN 14554-2 and ISO 22716 , e-IDAS and EMGP+ FSA scheme

The assessment procedure is based on the methodology of auditing of System Certification in the scope of accreditation and in accordance with EN 45011, EA-6/02 and valid prescriptions of accreditation entity. During the certification procedure is generally



LL-C (Certification)[®]

controlled quality assurance of welding processes in manufacturing, execution of steel / aluminium construction and welding of railway vehicles and ensuring the GMP+ FSA scheme - cosmetic products.

Machinery Devices

For the certification of machinery devices means to provide the assessment of conformity procedure EC type-examination whereby CB ascertains and certifies that a representative sample of machinery devices fulfils the requirements of Directive 2006/42/EC, or by full quality assurance system whereby the manufacturer who fulfils the obligations imposed ensures and declares that the products concerned meet the provisions of the Directive.

MDD – Medical Devices

For the certification of MDD means to provide EC Declaration of Conformity by assessment procedure of Full Quality Assurance system (*Annex II of the Directive 93/42/EEC*), procedure of Production Quality Assurance (*Annex V of the Directive 93/42/EEC*) and procedure of Product Quality Assurance (*Annex VI of the Directive 93/42/EEC*) by which CB ascertains and certifies that a representative sample of MDD fulfils the requirements of Directive.

Construction Products (CPR)

The procedure provides an assessment and verification of constancy of performance in accordance with Regulation (EU) No 305/2011 of the European Parliament and of the Council, Annex V (System 2+), further for the conformity assessment of construction products according to NV No. 163/2002 Coll. as amended by NV No. 312/2005 Coll. and No. 215/2016 Coll.

The CB provides the certification of factory production control (FPC), which is based on an initial inspection of factory and of factory production control and continuous surveillance assessment and approval of factory production control (FPC).

Furthermore, it is possible to use the evaluation system described in detail in Rule 15.7 for MDD-SW, but the evaluation / assessment of the quality system according to ISO 13485 and according to the requirements of the National Council or according to the EN 62304 standard as amended must not be neglected.

Toys

Assessment of conformity of Toys means to provide EC Declaration of Conformity by procedure EC type-examination whereby CB ascertain and certifies that a representative sample of Toys fulfils the requirements of Directive 2009/48/EC, Regulation of Government No. 86/2011.

Software for MDD

The assessment procedure is based on the methodology of auditing of System Certification in accordance with ISO 13485 and fulfilment of individual chapters of the Directive 93/42/EEC related to MDD and Directive 98/79/EC related to IVVD. The assessment system is set also by chapters and Annexes of the Directives and by request of client. LL-C provides assessment of MDD class.III by Annex No 2 of the Directive 93/42/EEC including examination of design of the product.

e-IDAS

The requirements for trust service providers (TSPs) in presenting compliance with the requirements necessary to obtain qualified status are regulated by the following documents: REGULATION (EU) No. 910/2014 OF THE EUROPEAN PARLIAMENT AND OF



LL-C (Certification)[®]

THE COUNCIL, Act 298/2016 Coll., Act 297/2016 Coll., Standard ČSN ETSI EN 319 403 V2.2.2.

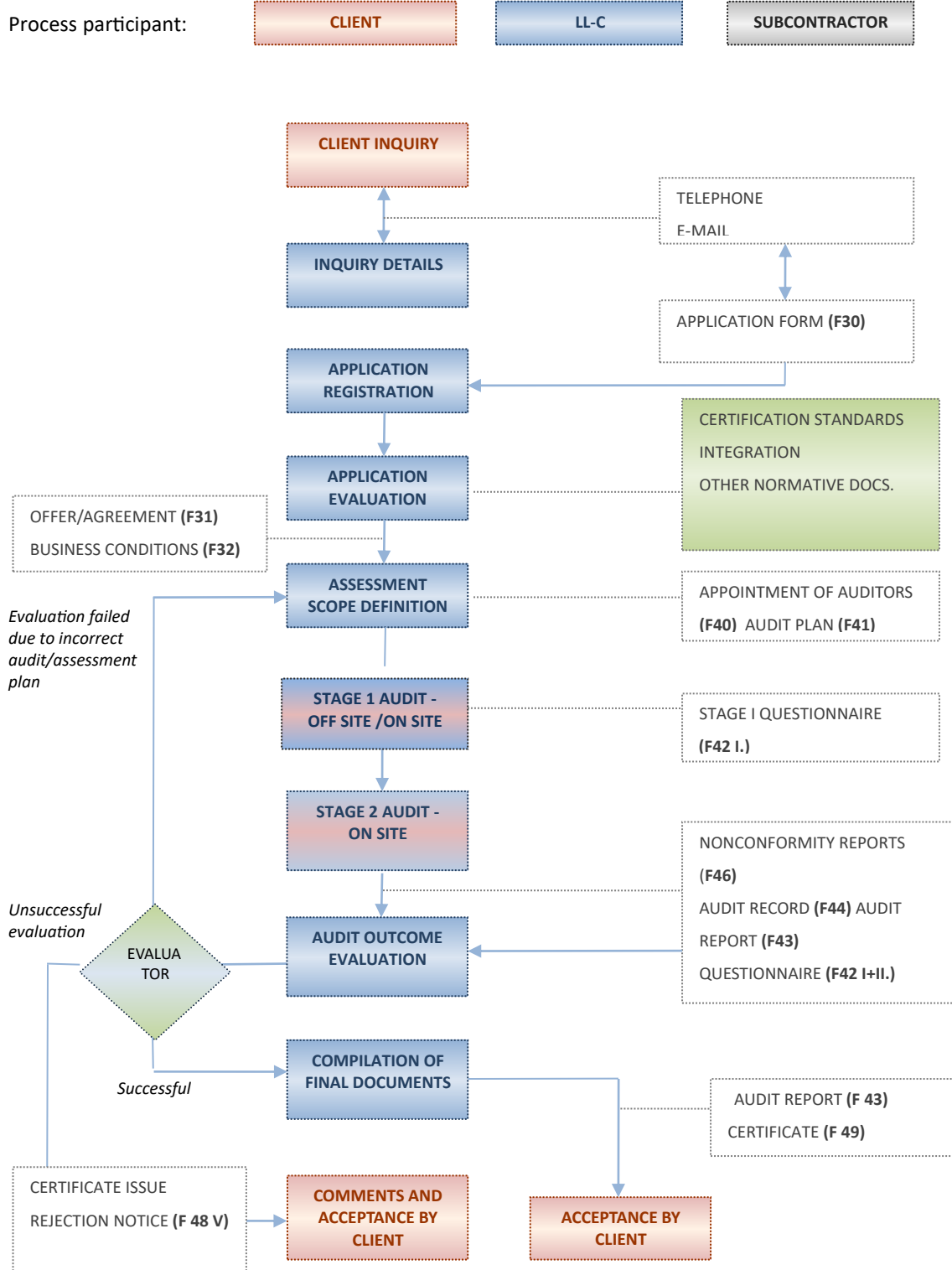
Simple pressure equipment (SPVD)

Conformity assessment of simple pressure vessels means the performance of conformity assessment by the EU type examination procedure, the design by which the CO determines and certifies that the product's simple pressure vessel model meets EU requirements in accordance with Government Regulation No. 119/2016 Coll.

V. Certification processes

A) Process of Management Systems Certification

Certification process diagram



LL-C (Certification)[®]

The certification process usually consists of:

- Inquiry and Application Questionnaire F30/F30.1
- Verification of the required documentation
- identify aspects, risks, processes of manufacture or the services provided (1st stage of audit, on-site or off-site)
- on-site assessment of the introduction and application of requirements of the standard at the head office and in branches of the applicant business (2nd stage of audit)
- evaluation of audit results

Each audit stage of the procedure during the period of validity of the certification contract are:

- the two stages initial audit and evaluation (certification audit)
- surveillance audits in the second and third year
- recertification audit (the audit re-assessment) at the end period of validity of the certificate to maintain a valid certification

The following articles describe the individual steps in certification procedure.

Inquiry / application registration /certification offer

Inquiry of any new client on the certification of management systems may be personally discussed with the LL-C staff or can be sent by email on info@ll-c.cz or by letter on contact address or sent via electronic form on the website www.ll-c.net. LL-C coordinator on the base of a written inquiry (a filled in Application Questionnaire F30/F30.1) conducts a review of the obtained information and verifies if CB has the competence and ability to perform the certification (the scope of accreditation). Review if it is not necessary to consider specific processes (e.g. welding, sterilization). This review is carried out in cooperation with the Head of CO.

Based on inquiry, data from the questionnaire and the current Tariff LL-C issues F31 Offer of management systems certification in written form and sends it to the address of the applicant. Business Conditions - F32 are the integral and mandatory annex of every offer.

Client who accepts any Offer for certification has to confirm the F31 and Business Conditions (F32). The signature of an authorized person for the applicant the offer is submitted and confirmed, as well as the signing and confirming of the attached Business Conditions makes full agreement/contract for the management system certification. The contract is generally governed by the provisions of the Commercial Code § 591 to the 600th in Czech Republic and accreditation criteria. Furthermore, this is provided information confirmation as well.

Confirming the order, the following process is initiated:

- is registered to the internal system certification case (contract), including information about the applicant
- is appointed lead auditor, who starts planning the audit (contact person authorized by the applicant, additional conditions, build an audit team, fix an audit date)
- the applicant is requested to submit his management manual or other document describing the management system at least 14 days before the audit.

In particular cases, client might rise a special request for back-to-back audit due to special circumstances. Those circumstance (e.g. long-distance travels, problematic



LL-C (Certification)[®]

travels, urgent situation – such as upcoming tender, etc.) have to be agreed by the CB before the audit is starts.

However, the possibility of back-to-back audits must be confirmed by the client – signing of F32 in advance.

In case, exception for back-to-back audit was not given, the 1st and 2nd stage are separated (no possibility of back to back audit).

If a client has any other requests, such requests shall be discussed with a responsible persona from LL-C(Certification) and held accordingly.

Auditors

Head of CB LL-C appoints the lead auditor, auditors, members of an audit team, technical expert and an evaluator of audit. They must be complied with the general qualification of auditors, including their competence and experience, reflecting the activity of the applicant and eventually any specific processes (e.g. welding), impartiality and independence. Appointment of auditor must be notified to the applicant in advance.

Client's documentation

The client's documentation must reasonably define the organizational structure of the applicant and a precise description of its activities. Above the management system manual documentation may also include activity procedures and work instructions. Documentation must take into account both direct and indirect requirements based on the standards and client's activities.

Audit documentation

Lead Auditor shall examine the documentation presented regarding completeness and requirements of the standard. In case of nonconformities or in case of FSSC scheme Area of Concer the applicant will receive a Report of Nonconformity and findings (F46) and must take corrective action and specify the date for their compliance. These nonconformities have to be removed before the Stage II of certification audit. Irrelevant anomalies may be clarified in during the audit. In FSSC scheme Area of Concern is clarified during 2nd stage of audit and must be closed or defined as NCRs. Documentation audit carried out by lead auditor is provided outside of the client's location. Documentation audit is carried out as part of the certification audit (Stage 1). The new revisions of the documentation are reviewed during surveillance, if necessary.

1st stage of Initial certification audit

1st stage of audit is an obligatory part and is carried out as part of the initial certification audit (1st stage). 1st stage of audit is performed to determine the preparedness of the client's location and status and the main conditions for the 2nd stage of audit. In FSSC 22000 scheme the time between audit stage 1 and audit stage 2 must not be longer than 6 months. 1st stage of audit will be repeated if longer interval will be needed.

The results from the 1st level of audits are presented in the form of the Protocol on Nonconformities - F46 and on specific forms.

In some circumstances, the 1st level, especially for the ISO 9001 standard, can be performed outside the applicant's company using questionnaires and telecommunication technologies. CAAT RAP.



LL-C (Certification)[®]

1st stage has to start with Opening meeting, which is followed by a site tour to investigate the following objectives:

- a) The client's management system documentation was reviewed, to sufficiently support the transparency of the client's management system;
- b) Specific workplaces, site conditions and client's personnel view about readiness for the 2nd stage must be checked;
- c) Client status and particulars with respect to the identification of the MS key performance or significant aspects, processes, objectives and operations must be reviewed;

ffffffffffffffffffff) The scope of the MS management system is to be confirmed by

- client's site
- processes and equipment
- levels of controls (especially of multisite clients)
- statutory and regulatory requirements;

gggggggggggggggggggg) Review of allocation of resources for 2nd stage and discussion with client details for 2nd stage;

hhhhhhhhhhhhhhhhhhhh) Information obtained were found sufficient for the statement that the system is in compliance with context of the standard - the plan of the 2nd stage with / without any alterations may be performed or not.

Results from 1st stage of audit are documented 1st stage report F 42.1 and on F46 Report of Nonconformities and other forms.

In case, exception for back-to-back audit was given, all parts of 1st stage of audit were done and results of 1st stage of audit were sufficient, the 2nd stage of audit can be carried out.

In some circumstances 1st stage of audit (particularly in standard ISO 9001) can be provided off-site of the applicant location using questionnaires and telecommunications technology. (RAP – remote auditing procedures).

Preparation and planning of audit

Lead auditor, in cooperation with the applicant draw up a program (plan) during the audit and inform the applicant in appropriate way. The plan contains all the information necessary for the applicant to prepare the audit. If necessary, the lead auditor can visit the client for plan specification. Likewise, an audit program is issued which displays the schedule of when the initial certification audit, the 1st surveillance audit, the 2nd surveillance audit and the re-certification audit shall be carried out, as well as the specification of the branches where the audit shall be carried out, and information about the most important processes to be assessed, aside from standard criteria.

CAAT-RAT / ICT method (methods of remote assessment and their approaches not only in times of pandemic crisis COVID 19). In case of FSSC 22000, FSSC 22000 Quality and GMP+ FSA certification schemes the remote assessment using ICT method will be organized according actual scheme owner directives in all phases of audit (initial or certification-Ist and IInd stage, surveillance and recertification audit).

As information and communication technologies become more sophisticated, it is important that CO staff are trained on how to use assessment methods using "ICT" in

LL-C (Certification)[®]

order to increase the efficiency and effectiveness of audits and to support and maintain the integrity of the process.

Methods of remote assessment using ICT technologies such as:

Teleconference, web meetings, interactive communication over internet, electronic online access to documentation and/or management system processes and others.

The audit may also be carried out remotely (the CAAT-RAT method) in which case the applicant shall send to the auditor or the assessor the electronic forms of the requested documents, and the auditor/assessor shall evaluate the documents outside of the applicant's registered office. This auditing method may not exceed 30 % of the scheduled duration of the audit, this does not apply to cases affected by the COVID 19 pandemic crisis.

ICT technologies that will be used as a tool for remote audit FSSC 22000 meeting all requirements of IAF MD 4:

- 1) Conducting interviews with people and reviewing on-site audit policies, procedures or records;
- 2) When using the ICT audit approach as set out in FSSC Annex 9

AUDIT ON SITE Opening meeting

This is the auditor interview with the management of the applicant and with his responsible for management systems.

The opening meeting goal is:

- Reaching a consensus in meters of plan, content and procedures of certification of CB and applicant
- Consultation of audit results (Stage 1)
- Determining the manner of communication between auditors and management
- Verifying whether the extent of the audit shall provide the auditors sufficient results for assessing
- A declaration of confidentiality and impartiality of auditing team

2nd stage of audit

The auditors in the assistance of the management or its representatives will examine the system of organizing units of the applicant in accordance with the plan, including amendments adopted during the Opening meeting. Auditors of the audit can use the questionnaire and verify whether the system is introduced and applied in conformity with the requirements of the specific standard and documentation of the client. Lead auditor shall communicate a preliminary report on the results after the audit. A team of auditors is not authorized to release the final conclusion of certification. The Audit Report contains the result of audit and other important information, the applicant will receive within 14 work/days. The applicant may comment on it within next following 14 days. If findings (non-conformities, deviations) are found in the system, the applicant must propose appropriate corrective actions and the date of their compliance; the date depends on the specific findings.

If the company has multiple functions in more than one location, the auditor must be aware of the company's headquarters and OFF-site activities.

Multi-site certification is allowed only in the subcategories:

- A –Animal Farming



LL-C (Certification)[®]

- E –Catering
- FI –Retail / wholesale
- G –Storage and distribution.

Evaluation of audit results

Lead Auditor shall forward to the evaluators/decision makers (e.g., Head of the certification body or his deputy) necessary documentation of the audit to an impartial evaluation and decision on certification.

Criteria for evaluation of audit results are as follows:

- Verification of compliance with the relevant standard
- Verification of compliance with the LL-C Rules
- Submission and completeness of audit results in the documentation of audit (report, questionnaire, reports of nonconformities)

The responsible evaluator clarifies the uncertainties with Lead auditor.

Based on findings review the applicant is informed if an additional audit will be needed to verify effectiveness of the action taken before granting the certificate.

The information for the applicant

In case that the evaluator/decision maker decides that the audit conclusion and other requirements of certification authorize the CB to grant or maintain the certificate the applicant will receive a certificate (in the case of the initial audit) and Audit Report on what additional conditions have to be fulfilled before issuing the certificate (maintaining in case of follow up audits).

In case that the evaluator/decision maker decides that the audit results do not allow the CB to grant the certificate or maintain the valid certificate the decision is notified to the applicant, including the reasons for the decision.

The applicant may appeal to the Head of the CB and ask to the change the decision taken.

Certification contract

A certification agreement must be concluded between the certification body and the organization applying for certification with a detailed description of the scope of the certificate and a reference to all relevant system requirements. This agreement must contain details or references to agreements between the CB and the organization, which include, but are not limited to:

- 1) Ownership of the certificate and the content of the audit report will be held by the CB;
- 2) Conditions under which the certification contract can be terminated;
- 3) The conditions under which the certificate may be used by a certified organization;
- 4) Conditions of confidentiality in relation to information collected by the CB during the certification process;
- 5) The certified organization allows the CB to share information regarding the certification and audit process with the FSSC Foundation or Scheme Owner, the GFSI or government agencies, if required;
- 6) Non-compliance management procedures;
- 7) Complaints and appeals procedures;



LL-C (Certification)[®]

- 8) Inclusion of information about the certified status of the organization on the LL-C web and web scheme (FSSC 22000, GMP + FSA, etc.) and on the portal or other system that uses the given schemes;
 - 9) Cooperation in enabling the evaluation of the auditor (witness - witness audit) by the Accreditation Body and / or the Foundation, if required;
 - 10) Communication obligations of certified organizations towards the Certification Body (CO) within 3 working days concerning:
 - (a) any significant changes that affect compliance with the system requirements and seek advice from the CO in cases where there are doubts about the significance of the change;
 - (b) Significant events that have an impact on the management system (FSMS, FSQMS, etc.), legality and / or integrity of the certification, including legal proceedings, prosecutions, situations that pose a serious threat to food safety, quality or integrity of certification due to natural disasters; or man-made disasters. (eg war, strike, terrorism, crime, flood, earthquake, electronic attack on computers, etc.);
 - c) Public events related to food safety (eg public convening, disasters, food safety outbreaks, etc.);
- ffffffffffffffffffff) Changes in the name of the organization, contact address and details of the site;
- gggggggggggggggggggggg) Changes in the organization (eg legal, business, organizational or ownership status) and management (eg key management, decision-making or technical staff);
- (f) changes in the management system, scope of operations and product categories covered by the certified management system;
 - g) Any other change that makes the information on the certificate inaccurate

The contract of certification of management systems, which manages the rights and obligations of applicant and CB is concluded confirming the F31 Offer of Management Systems Certification and F32 Business Conditions by the applicant. The applicant must confirm the both before starting the audit (Stage 1). For granting a certificate the contract is mandatory.

Certification

Once all criteria have been met the LL-C grants certification in the form of a certificate, the applicant gets official certificates (2 original sets in the national language of the applicant and 2 originals in English). For additional copies and for foreign language versions may be charged additional fee. The certification is valid for duration of not more than 3 years from the date of approval and is subject to the agreed Business Terms and to requirement of monitoring the fulfilment of requirements of relative standard (standards).

Use of LL-C logos and marks

Use of the LL-C logos and marks is regulated under the terms of Business Conditions - F32. Upon obtaining a valid certificate, the client is entitled, for the duration of the certificate validity, to use an approved logo of the certification body or private scheme owner (FSSC 22000, including FSSC 22000 Quality, GMP+ document A3 etc.).

In case of private certification schemes the use of logo will be according their own documents (GMP+ document A3, FSSC 22000 document Part IV, etc.)

The LL-C approved logo shall not be used on a product or product packaging seen by the consumer or in any other way that may be interpreted as denoting product conformity.



LL-C (Certification)[®]

The use and placement of the logo must not, however, create confusion between the client and the certification body, or convey a false impression that the certification applies to a specific product instead of the management system, unless it is clear that certified standard is for the product certification.

Certified subject must comply with the terms, including the use of logos and marks referring to the certification on promotional items.



LL-C (Certification)[®]

Maintenance of certification

In order to maintain the valid certificate LL-C provides the annual surveillance audits to determine the effectiveness of the system. LL-C executes these audits so that the surveillance audit following initial certification should not be more than 1 year from the last day of the stage 2 audit or of the last surveillance audit.

If the surveillance audit findings show that the client's management system doesn't fulfil the requirement of the standard the client gets the possibility to make corrective actions in determinate date. LL-C verifies and decides if the corrective actions are sufficient for maintenance of certification.

Before the end of its validity, and if the client wishes to continue with the certified management system with the LL-C, LL-C recertification/renewal audit must be conducted. Renewal (or recertification) audits are planned in the third year and conducted to evaluate and confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification so that the new certificate could be granted before the end of validity of the old one.

The procedures and guidelines are consistent with those for initial audit. Any changes in client's organization (e.g. change in number of sites), activities or documentation must be supplied at least 14 days before starting audit.

LL-C (Certification)[®]

B) Process of Product Certification

Diagram certifikačního procesu – certifikace výrobku/procesu

(I-B, I-C) – posuzování systému řízení, správné výrobní praxe, ...

Účastník procesu:

ZÁKAZNÍK

LL-C

SUBDODAVATEL

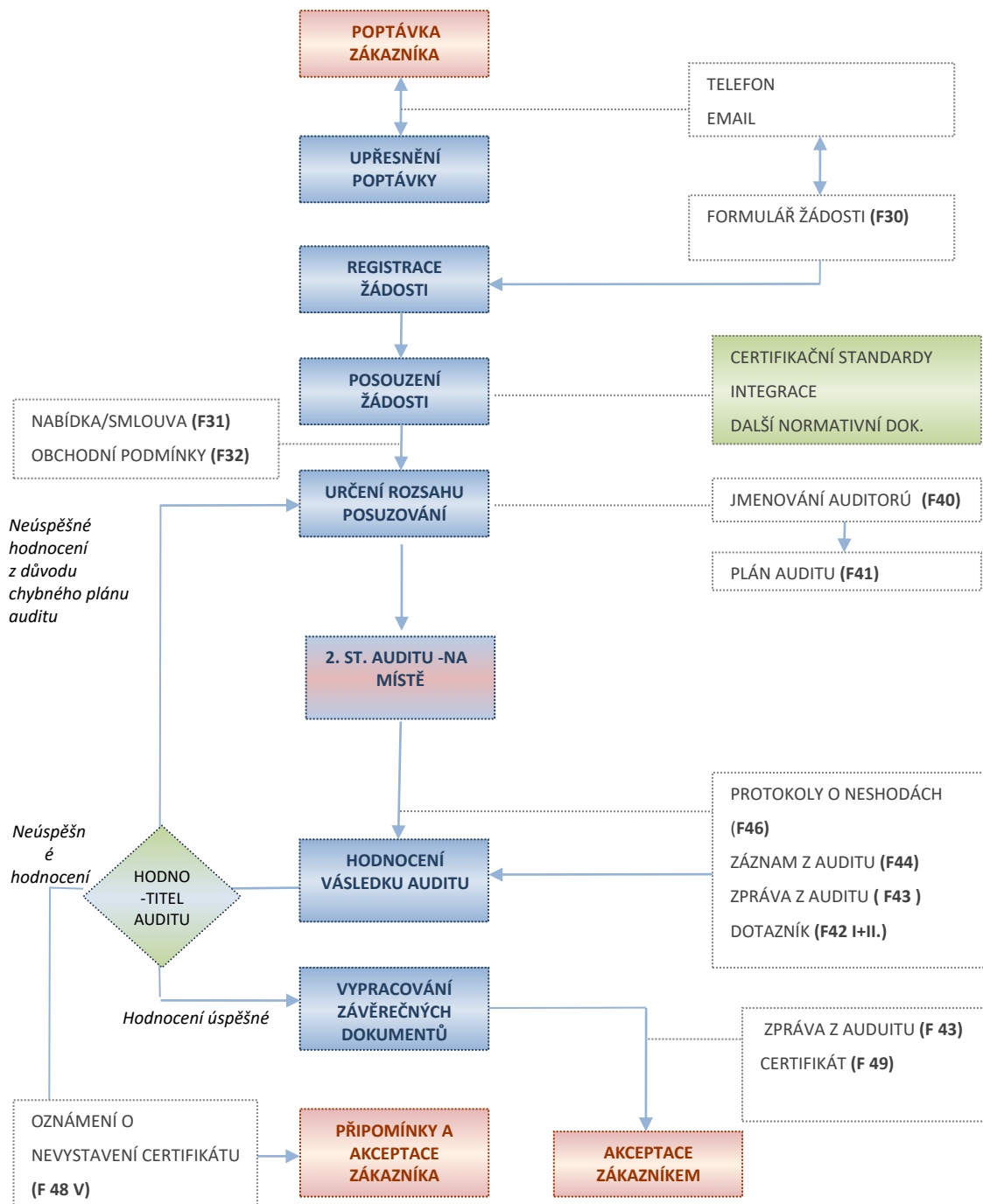
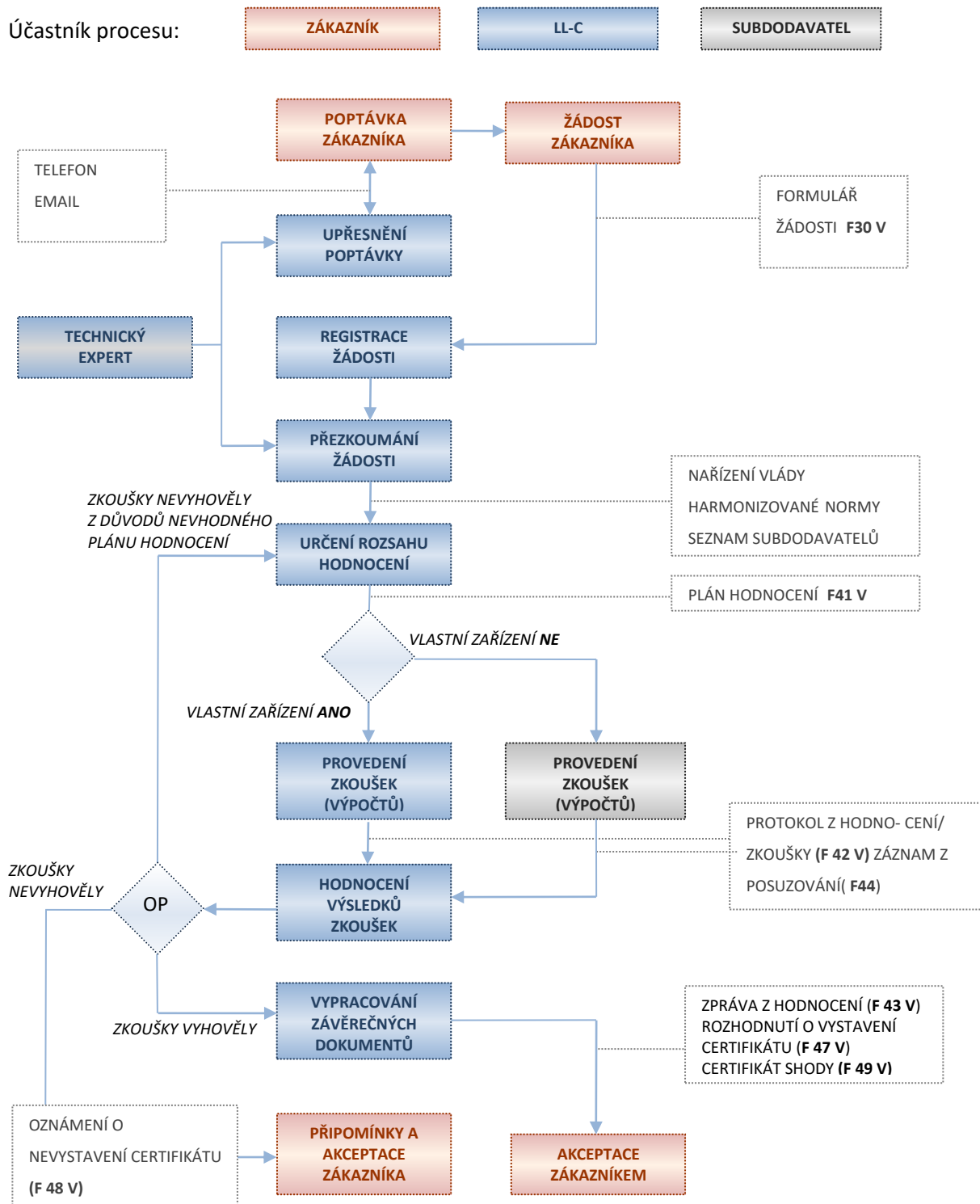


Diagram certifikačního procesu – certifikace výrobku/procesu

(I-B, I-C) – zkoušení vykonané CO



*The certification process diagram does not apply to medical devices certification process, which is described separately in Rule 15.11 document.

The certification process usually consists of:

- Inquiry and elaboration of Application F30V
- Verification of the required documentation
- Elaboration and agreement of Certification Offer F31V
- Evaluation process
- Certification review and
- decision on certification

Each stage of the procedure during the period of validity of the certification contract are:

- initial evaluation, review and decision on certification by DM (Decision maker)
- surveillance if requested by certification scheme
- renewal of certification (recertification/renewal evaluation) in the end of period of certification validity

Inquiry / application registration /certification offer

Inquiry of any new client on the product certification may be personally discussed with the LL-C staff or can be sent by email on info@ll-c.cz or by letter on contact address or sent via electronic form on the website www.ll-c.cz. LL-C coordinator on the base of written inquiry conducts a review of the obtained information and verifies if CB has the competence and ability to perform the certification (the scope of accreditation), all based on F30 V.

The documentation at the stage of application for certification must adequately define the organizational structure (including geographical locations and local activities) of the applicant and a description of its activities, which are essential for certification, for which application has been made. Documentation may include, in addition to the manual the procedures and work instructions. Documentation must take into account both direct and indirect requirements based on standards used and the subject matter.

Coordinator reviews the documentation to ensure that the product is in the scope of LL-C accreditation and if the CB has the competence and capability to perform the certification activity. With the positive conclusion based on inquiry, data from the questionnaire and the current Tariff, LL-C issues F31 Offer of Product Certification in written form and sends it to the address of the applicant. Business Conditions - F32V are the integral and mandatory annex of every offer.

Client who accepts an offer for certification has to confirm the F31 and Business Conditions F32V. The signature of an authorized person for the applicant the offer is submitted and confirmed, as well as the signing and confirming of the attached Business Conditions makes full agreement/contract for the Product Certification. The contract is generally governed by the provisions of the Civil Code Nr. 89/2012 Sb. § 2652 až § 2661 in Czech Republic and accreditation criteria. Furthermore, this is provided information confirmation as well.

Confirming the order, the following process is initiated:

- is registered to the internal system certification case (contract), including information about the applicant

LL-C (Certification)[®]

- is appointed Lead evaluator, who starts planning the evaluation activities (contact person authorized by the applicant, additional conditions, build an evaluation team, fix a date of evaluation, etc.)
- the applicant is requested to submit the Technical documentation of the Product (product documentation, design drawings, the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product, the results of the design calculations, risk analysis, investigations, technical tests, etc. at least 14 days before the evaluation.

Evaluators

Coordinator of CB LL-C appoints the Lead evaluator and members of an evaluation team, technical experts and DM – decision maker which is responsible for review and decision related to certification. They must be complied with the general qualification of evaluators, including their competence and experience, reflecting the specific product in question, impartiality and independence. Appointment of Lead evaluator must be notified to the applicant in advance.

Evaluation activities

Evaluation activities consist in the conformity assessment of requirements covered by the scope of certification and other requirements of certification scheme.

Evaluation of conformity shall be governed by different procedures depending on the type of product and consists mainly of:

- examination of all elements, requirements and provisions adopted by the manufacturer for his quality system, if they are documented in a systematic and orderly manner in the form of written policy statements and procedures and if they premise uniform interpretation of the quality policy and procedures such as quality programmes, plans, manuals and records.
- Assessment of quality system assurance to determine whether it satisfies the arrangement documentation requirements.
- Inspection on the manufacturer's premises and to ensure that it meets the relevant requirements of health and safety.
- examine and assess the documentation and verify that the type has been manufactured in conformity with that documentation.
- Appropriate inspections and the tests necessary to verify to verify compliance with the basic technical requirements for health and safety
- Appropriate inspections and the tests necessary to verify whether, if the manufacturer has chosen to apply the harmonised standards, these have actually been applied

In case of nonconformities the applicant will receive a Report of Nonconformities (F46) and must propose corrective action and specify the date for their compliance.. These nonconformities have to be removed before the end of evaluation. The irrelevant anomalies may be clarified in during the assessment.

For evaluation, the evaluators use a questionnaire to assess compliance with the relevant standards, regulations and government directives and documentation of the applicant. Lead Evaluator shall communicate a preliminary report on the results after the evaluation. Evaluating team is not authorized to release the final conclusion of certification. The Evaluation Report containing the result of audit and other important information, the applicant will receive within 14 work/days. The applicant may comment



LL-C (Certification)[®]

on it in following 14 days. If findings (non-conformities, deviations) are found, the applicant must propose appropriate corrective actions and the date of their compliance; the date depends on the specific findings.

Review and certification decision

Lead Evaluator shall forward to the decision maker (e.g., Head of the certification body or his deputy) all documentation related to evaluation to an impartial assessment and decision on certification.

Criteria for assessment and review the results related to evaluation are as follows:

- Test records, questionnaire
- Calculation record and reports (if requested by the scheme)
- Evaluation Report F43V
- Verification of compliance with the LL-C Rules
- Submission and completeness of evaluation results in the documentation (report, questionnaire, reports of nonconformities)
- Corrective actions on findings during the evaluation

The responsible DM clarifies the uncertainties with Lead Evaluator.

Based on findings review the applicant is informed if additional tests will be needed to verify effectiveness of the corrective action taken before granting the certificate. The DM reviews the results of additional evaluation.

The information for the applicant

In case that the DM decides that the evaluation results and other requirements of certification authorize the CB to grant or maintain the certificate the applicant will receive a certificate (in the case of the initial evaluation) and Evaluation Report, eventually report on what additional conditions have to be fulfilled before issuing the certificate (maintaining).

In case that the DM decides that the evaluation results do not allow the CB to grant the certificate or maintain the valid certificate the decision is notified to the applicant, including the reasons for the decision.

The applicant may appeal to the Head of the CB and ask to the change the decision taken.

Certification issue

Ones all criteria have been met the LL-C grants certification in the form of a certificate, the applicant gets official certificates (2 original sets in the national language of the applicant and 2 originals in English). For additional copies and for foreign language versions may be charged additional fee. The certification is valid for duration of not more than 5 years from the date of approval and is subject to the agreed Business Terms and to requirement of monitoring the fulfilment of requirements of relative standard (standards).

Use of LL-C logos ad marks and private schemes (FSSC, GMP+ FSA, IFS)

Use of the LL-C logos and marks and private schemes (FSSC, GMP+ FSA, IFS) is regulated under the terms of Business Conditions - F32. Certified subject must comply with the terms, including the use of logos and marks referring to the certification on promotional items. Use of private schemes logo is guided by its documentation and requirements (GMP+ A3 GMP+ Logo 's and/or Trademarks, FSSC 22000 etc.)



LL-C (Certification)[®]

Maintenance of certification

Surveillance and remote surveillance audits

If required by the certification scheme are in order to ensure ongoing maintenance of demonstrating compliance with the requirements of the product carried out periodic surveillance. LL-C executes these surveillances so that the surveillance audit following initial certification should not be more than 1 year from the last day certification or of the last surveillance.

Each surveillance for the relevant management system standard shall include:

- a) Internal audits and management review;
- b) A review of actions taken on nonconformities identified during the previous audit;
- c) Complaints handling;
- ffffffffffffffffffff) Effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
- gggggggggggggggggggg) Progress of planned activities aimed at continual improvement;
- hhhhhhhhhhhhhhhhhhhh) Continuing operational control;
- iiiiiiiiiiiiiiiiiiii) Review of any changes;
- jjjjjjjjjjjjjjjjjjjj) Use of marks and/or any other reference to certification.

If the surveillance findings show that the manufacturer doesn't fulfil the obligations imposed by the approved quality system then he gets the possibility to make corrective actions in determinate date. LL-C verifies and decides if the corrective actions are sufficient for maintenance of certification.

Note: For ANAB accredited standards it is unlikely that a surveillance audit duration will be is less than 1 audit day.

Significant changes in the organization (e.g. change in the number of branches), business and main documentation must be submitted to LL-C at least 14 days before the start of the audit.

As information and communication technologies become more sophisticated, it is important that CO staff be able to use assessment methods using "ICT" to increase the efficiency and effectiveness of the audit and to support and maintain the integrity of the audit process.

Remote assessment methods using ICT may include the following approaches:

Teleconferencing, Web meetings, Interactive communication via the Internet, Electronic remote access to management system documentation and / or processes and other approaches

The aim is to provide a sufficiently flexible and non-prescriptive methodology to meet the needs of industry by allowing client organizations to use CAAT-RAT to improve the traditional audit process.

The audit can be performed remotely, when the responsible person is not present and is abroad, for example. The interview is then conducted with the help of Skype, Viber, WhatsApp, and other ICT tools, where the applicant sends electronic versions of the required documents to the auditor or assessor and he evaluates them outside the



LL-C (Certification)[®]

applicant's workplace, etc. This audit method must not exceed 30% of the client's planned audit time.

The ICT/CAAT method must be agreed in before any part of the audit (part of Auditor Appointment) starts; IAF MD 3 – current version. Audit is then conducted in according with requirements of IAF MD 4 (current version).

IF any ICT technology used for CAAT-RAT or remote audit date, time have to be mentioned, also specification of technology used (which one).

Renewal of certification

Before the end of its validity, and if the client wishes to continue with the certified product by LL-C, LL-C renewal evaluation must be conducted.

Planning must take into account the time needed to evaluation and decision so that the new certificate could be issued before the expiration of the old one.

The manufacturer must inform the CB any plan for substantial changes to the quality system verify whether after these changes the quality system still meets the requirements and this at least 14 days before starting renewal evaluation.

GMP + FSA scheme certification procedures are governed by the RULE 15_48 procedure.

VI. Suspension or withdrawal of certificate

Suspension Certificate

In case of violation of certification contract of the client and the subsequent examination of the severity of the violation, the certificate shall be suspended for a period specified by LL-C. This may arise for example in the following cases:

- surveillance or any other sources findings show that the client's management system persistently or seriously failed to meet certification requirements, doesn't fulfil the obligations imposed by the approved management system, agreed corrective action has not been properly applied
- surveillance audit could not be started on time (as a certified client refuses to perform surveillance)
- certified client is in insolvent circumstances or in anticipation of bankruptcy
- certified client use the certificates in unauthorized manner.

The suspension shall be communicated to the client by the registered letter/certified mail and published on the website of the CB. The holder may appeal within 30 days to the Head of the CB. The suspension of LL-C ends immediately if the applicant demonstrates needed actions within a specified period.

Termination/withdrawal of certification

If the client, despite instructions from LL-C fails to fulfil its obligations of the contract, for example, will not take corrective action or fails to comply with the above-mentioned shortcomings, LL-C immediately terminates the validity of the certificate. This notifies to the client; requires the return of original certificates by registered mail and public that information. Other reasons for termination may be, for example:



LL-C (Certification)[®]

- surveillance audit shows that the essential requirements for the system are not met
- client's request for termination
- the client does not produce products related to the certification (change of technical parameters, doesn't fulfil the requirements)
- the client fails to meet financial obligations to LL-C
- another violation of Business Condition F32 from the client.

The certificate withdrawal is published on CB websites.

In case of suspension, withdrawal or cancellation of certificate owners of private schemes will be informed in all information will be entered into their databases as well (FSSC 22000 Portal, GMP+ FSA database etc.)

VII. Transfer of accredited certification

Only certificates issued within the scope of accreditation by the signatories MLA – EA, IAF, PAC, IAA may be considered for transfer if the respective certificate shall have been issued by a body that shall have been accredited by an accreditation body that is the signatory only of a regional MLA, then such transfer shall be limited only to certification bodies accredited by bodies involved in said regional agreement. Organizations that are holders of certificated that are not covered by such accreditation shall be treated as new clients.

Re-examination Before the Transfer of Certification

If a query regarding the transfer of certification shall have been received, the certification coordinator shall appoint an audit coordinator with qualification for the respective area and prepare and register a transition plan which includes communication with the issuing body, and assessment of the documentation for the transfer via the transfer report.

Regarding the communication with the issuing body, the certification coordinator shall contact the issuing body via IW in order to request documentation and confirm the validity of the certificate and other critical matters relevant to the procedure. Among the documentation that shall be requested is the following:

- Audit plan.
- Audit reports.
- Checklists.
- Non-conformities and/or other audit findings.
- Corrections, root cause analysis, and corrective action plan to non-conformities.
- Audit program.
- Certificates.

The date and e-mail of the communication to the issuing body are registered in IW. The certification coordinator shall upload evidence of the communication (screenshot or file) with the issuing body and upload the provided documents on IW.

Notwithstanding the foregoing, LL-C (Certification) will continue the transfer according to the customer's requirements if no answer is received within three audit working days since the dispatch of the communication using the documentation provided by the client's organization. In this regard, if such a situation occurs, the certification coordinator will send an e-mail via IW to the accreditation body of the issuing body letting it know the situation. The date and e-mail of the communication to the accreditation body are



LL-C (Certification)[®]

registered in IW and evidence (screenshot or file) is uploaded by the certification coordinator.

Regarding the assessment of the documentation of the transfer, the examination carried out by the audit coordinator shall cover the following aspects and its conclusions shall be documented in the transfer report:

- confirmation that the certified activities of the client fall within the scope of accreditation of LL-C (Certification) Czech Republic a.s.;
- reasons for requesting the transfer;
- whether the workplaces that is requesting the transfer of certification are owners of an accredited certificate that is in force as regards authenticity, term of validity and the scope of activities covered by the management system certificate.
- evaluation of the latest reports from a certification or re-certification audit, reports from follow-up supervision and all significant non-conformities which shall have been discovered within said audits or supervisory visits. This evaluation shall also include all and any further documentation that shall be available and concern the certification process, i.e. hand-written notes, checklists etc. If no reports from the last certification or re-certification audit shall be available, or if the follow-up supervisory audit shall be postponed, the organization shall be regarded as a new client;
- received complaints and measures taken;
- state within the current certification cycle;
- all and any existing liabilities of the organization in relation to regulatory bodies as regards compliance with laws.

Decision Regarding Transfer

Certification, which shall be known to have been suspended or to be at the risk of being suspended, shall not be accepted for transfer. If the receiving certification body shall be unable to verify the state of certification with the issuing certification body, LL-C (Certification) will continue the transfer according to the customer's requirements with the documentation provided by the organization.

If no significant or potential problems shall be discovered during the re-examination before the transfer, the certificate may be issued within the ordinary decision-making process. If the CO shall decide regarding the taking-over of an accredited certification without performing a certification or a re-certification audit, the program of the follow-up supervision shall be based on the previous certification mode.

If the decision shall have been made to take over a certificate, an offer of supervision over the maintenance of the system shall be sent simultaneously, and after this offer shall have been confirmed, a certificate shall be issued.

VIII. Responsibility of Certification Body

Confidentiality

LL-C considers all information and documentation of the certificate holder or applicant to be confidential.

Appointment of auditors and their qualifications (management systems certification)

For the certification of management systems certification body selects leading auditors with appropriate qualifications and relevant professional experience. The auditor's skills are continuously updated by the internal and external training.

Auditors or appointed decision maker/the evaluator (Head of the certification body or his deputy) involved in certification must not participate in the consultations in introduction



LL-C (Certification)[®]

of applicant's system or otherwise connected in a way that does not guarantee his impartiality. Appointments of auditors are proposed to the client for approval. The applicant has the option to refuse individual auditors. However, it must explain his motivation that the head of LL-C consider and adopt final decision. In case of customer's complaints, the head of LL-C act according to the internal Quality Manual Rule 01 (below mentioned). External experts and auditors are also bound by confidentiality under contract with LL-C.

Appointment of evaluators and their qualifications (product certification)

For the certification of products, the Head of CB selects evaluators with appropriate qualifications and relevant professional experience. The evaluator's skills are continuously updated by the internal and external training.

Evaluators or DM (Head of the certification body or his deputy) involved in certification must not participate in the consultation activities in client's organization or not to be involved in an organization that has a relationship with the applicant for certification for at least two years, or to be engaged in product development, which assesses.

The evaluator / assessor, technical expert, unless is the permanent employee of CB, in assessing under the conditions specified in the Agreement on cooperation that contains provisions covering ensuring confidentiality and avoidance of conflicts of interest in accordance with **Rule05 – Act and Behaviour of CB personnel**.

Appointments of evaluators are proposed to the client for approval. The applicant has the option to refuse individual evaluators. However, it must explain his motivation that the head of LL-C consider and adopt final decision. In case of customer's complaints, the Head of LL-C act according to the internal **Quality Manual Rule 01** (below mentioned). External TE and evaluators are also bound by confidentiality under contract with LL-C.

Records

LL-C certification retains all records, documents and reports for a period of 3 years after the end of their validity for management systems certification. For product certification retains records, complete documentation and evaluation reports as required by related standard or Directive.

For the purposes of authorities of surveillance on market (in CR ČOI) and on medical devices (in CR SÚKL) must have retained complete documentation, which was part of a conformity assessment of MDD. This documentation of the manufacturer or his authorized representative shall keep for at least 5 years (in the case of implantable MDD for 15 years) from the date of manufacture of the last product.

SJ-PK - in case of issuing a certificate for SJPK in accordance with the requirements of LL-C Certification a.s. on behalf of the (coordinator), informs the **Ministry of Transport** of all discrepancies and breaches of certification within fifteen days of the issuance of the certificate, or of the last supervisory audit and other activities.

Certification Publications

LL-C at regular intervals, publish a certificate holder on the websites www.ll-c.info on the basis of the client's Tax Identification Code. In the case of suspension and withdrawal of certificate is this information published immediately.

In private certification schemes (FSSC 22000, including FSSC 22000 Quality, GMP +), information about clients and certification dates, etc., are uploaded to its IS of the scheme owner within 14 days after each event.



LL-C (Certification)[®]

Changes on certificates (activity, address, et.c) suspension, withdrawal or cancelation of certificates are directly send to databases of private schemes (FSSC 22000 Portal database, GMP+ FSA database etc.)

Business Continuity certification specification

In case any client is affected by a natural disaster or any other situation affecting business continuity, steps taken in this regard has to be taken.

If such situation occurs, client will receive F33 – Questionnaire Business Continuity. Based on information from F33 – Questionnaire Business Continuity, CB will evaluate appropriate methods and steps to be taken and will communicate with the client by phone or via email.

Further, client will be informed about steps that will be taken and about additional documentation needed, which will allow an off-site assessment; documentation such as management review meeting minutes, corrective action records, results of internal audits and status of process controls. Based on this documentation assessment we will be able to determine continuing suitability of the certification (short-term basis only).

This procedure contains:

- proactive communication between the affected organization and CB
- description of steps that will be taken (above), based on information from F33 - Questionnaire Business Continuity;
- CB will communicate with client time schedule and based on this will evaluate the latest date before withdrawal of certification will become mandatory;
- every such case will be looked at individually based on information obtained and will be communicated with client (timing, method, re-instatement activities and assessment);
- CB has the right of possible amendments to client to oversight plans on case-by-case basis, always in accordance with CB procedures;
- when access to the affected area is re-established, CB oversight plans for surveillance/recertification activities reestablishment

If contact with the organization cannot be made, CB will have to follow its internal policy and take appropriate steps (section VI. Suspension or withdrawal of certificate).

IX. Responsibility of Certification Holder

A) Certification of management systems

Management System supervision

Certifying the management systems the holder assumes an obligation to review the effectiveness of the system, providing of regular and documented internal audits. If the holder found failure of comply the standard, he must take on his own corrective actions. Continuous monitoring of LL-C does not exclude the holder from above mentioned obligatory requirement.

Assistance for the LL-C auditors

The holder is obliged to allow the LL-C to carry out a timely audit and to provide assistance to auditors in the audit. Auditors must have access to any premises, including the scope of certification and to allow the auditors to review all relevant documents.

Modifications of the holder's management system

RULE 03, Revision 42, Page 28 (total 33)

LL-C (Certification) Czech Republic a.s., Pobřežní 620/3, Praha 8 - Karlín 186 00
M.C., section B, inset 22724, IC 27118339

LL-C (Certification)[®]

The holder is obliged to immediately inform the LL-C of any change management system, or modifications, affecting the extent of its validity, e.g.

- In the case of organizational change (change of name, place of operation, sale or purchase of an enterprise or its parts, an action for bankruptcy, the scope of certification, etc.)
- In case of substantial changes of key product activities, the change of services
- In case of substantial large changes in the documentation.

LL-C examines changes. In response to the character and extent may be decided an extraordinary audit to carry out.

B) Certification of products

The manufacturer must affix the CE marking in accordance with Directive and draw up a written declaration of conformity.

The holder/manufacturer of certificate of machinery device must constantly ensure that the machinery meets the corresponding state of the art.

The certificate holder of the construction product must consistently ensure that the referred construction product corresponds to the production technical parameters specified on the certificate and in the report. In the event of changes in production processes or other essential technical parameters of the construction product, the certificate holder is obliged not to include the changed construction product with the existing certificate. The certificate holder is required to notify any changes to the certification body.

The certificate holder shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

Assistance for the LL-C evaluators

The holder is obliged to allow the LL-C to carry out a timely evaluation and to provide assistance to evaluators in the evaluation tasks. Evaluators must have access to any premises, including the scope of certification and to allow the evaluators to review all relevant documents.

Modifications of the holder's management system

The holder/manufacturer must inform LL-C of any plan for substantial changes to the quality system or the product-range covered. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements or if additional evaluation of conformity is needed.

The holder/manufacturer shall inform LL-C which issued the EC design-examination certificate of any such changes made to the approved design. This additional approval must take the form of a supplement to the EC design examination certificate.

The holder is obliged to inform the LL-C of any change management system, or modifications, affecting the extent of certification validity, e.g.

- in case of organizational changes (change of name, place of operation, sale or purchase of a business or its part, the application for bankruptcy, the scope of certification, etc.)
- In case of substantial changes of key product activities, the change of services

LL-C (Certification)[®]

- In case of substantial large changes in the documentation. LL-C examines changes. In response to the character and extent may be decided an extraordinary surveillance to carry out.

X. Application of Certification Rules modifications

The certification system of the LL-C is based on the requirements of applicable standards and accreditation requirements. All certification holders must be informed in case of their changes, when the certification system must be modified. This may occur in the following cases:

- Revision and modification of certification standards
- Modification if accreditation rules (such as changes in the surveillance period, expenses related to accreditation and audits, etc.).

In case that the holder does not agree to the specific change the contract of certification ends by the modification approval date.

XI. Financing and certification fees

Fees for certification are set out in the tariff of LL-C, which is based on the applicable requirements "guidelines for accreditation in accordance with ISO 17021 (MPA). As part of this accreditation must LL-C fulfil these requirements, especially concerning the time range of audit.

Fees for certification or any other extra costs are the subject of the certification offer.

Before starting the audit/evaluation the proforma invoice price must be paid in - accreditation condition, which payment shall not be bound by the conclusion of the certification process. See F32.

XII. Complaints and Appeals Procedure

Appeals

Clients may appeal the LL-C decision to the Head of CB within 30 days. He must establish a 3-member Appeals Committee of auditors/evaluators and experts (including himself), who were not involved in the certification activities related to complaint or appeal. The committee reviews and verifies all necessary information and decides, voting with simple majority.

Complaints

Any third party can complain to LL-C on the certification decision. It followed a similar procedure as the appeal depending on the type of complaint.

In case of an extraordinary audit is the Appeals Committee is convened only after the disputation of its outcome.

The precise procedure for receiving complaints and appeals, their evaluation and implementation is documented in Rule12 - Rules of Appeals Committee.



LL-C (Certification)[®]

XII. Commitment information

Due to the SJ-PK certification, LL-C undertakes to provide the Ministry of Transport of the Czech Republic with information on all classified non-conformities found in the accreditation process and supervision of the activities of the certification body. The given obligation is fulfilled according to the requirements of the methodical instruction and information in Rule 04.

The procedure for the implementation of the joint audit or its system activities is excluded and is carried out only under the full direction of LL-C Certification a.s.

The Ministry of Transport is informed of all information and findings by e-mail immediately within 15 days of the end of the supervision process. The newly printed / changed existing certificate is sent to the Ministry of Transport immediately within 15 days.

FSSC and GMP + FSA PORTAL DATA AND DATA OWNERSHIP DOCUMENTATION

- a) The (certified) organization is the owner of the audit report, while the CB is responsible for the data of the report.
- b) The certificate holder is a (certified) organization, not the owner. CB is the owner of the certificate data.

DATA QUALITY CONTROL

The CO must have a data quality control process in place that guarantees the quality of the CB portal data. The quality parameters include at least the following:

- a) Completeness: All mandatory data have been registered on the Portal;
- b) Timeliness: All data were registered on the portal within the required time limits;
- c) Validity: The values of the registered data meet the requirements of the scheme;
- Accuracy: Data is a true representation of actual facts related to the full audit and certification process;
- Consistency: The registered data on the Portal represent a real representation of the data stored in the internal system (s) of the certification bodies.

Certification Body - PORTAL

- a) At the request of the certified organization, the certification bodies shall actively provide the certified organization with access to the related organization profiles, audit and certification registered on the CO portal using the available function.
- (b) the certification body shall ensure that access to the certified organization is granted only to authorized persons.

List revisions and motivations

Rev.	Date	Motivation	Insert	Approved by
1	4.1.2004	First publication	M.Krutský	M.Krutský
2	15.6.2004	Page 8	M.Krutský	M.Krutský
3	27.9.2004	Page 3-8, 10	M.Krutský	M.Krutský
4	30.5.2005	Page 3-8, 12-13	M.Krutský	M.Krutský
5	12.10.2005	Page 8	M.Krutský	M.Krutský
6	28.2.2006	Page 1	M.Krutský	M.Krutský
7	1.7.2008	Page 3-12	M.Krutský	M.Krutský
8	20.8.2009	Page 3-12	M.Krutský	M.Krutský
9	13.1.2010	Page 3-12	M.Krutský	M.Krutský
10	29.11.2010	Page 3-12	I.Angelovski	M.Krutský
11	10.12.2012	Page 2- 12	I.Angelovski	M.Krutský
12	22.05.2013	Page 2, 4, 5, 7	I.Angelovski	M.Krutský
13	1.12.2013	Revision of all document	B.Kuchtová	M.Krutský
14	10.2.2014	Page 2,20	L.Holub	M.Krutský
15	18.2.2014	Page 19	B.Kuchtová	M.Krutský
16	25.4.2014	Strany 13, 14	D.Tokar	M. Krutský
17	9.4.2015	Revize a úpravy celého dokumentu	B.Kuchtová	M. Krutský
18	5.11.2015	Strana 8	D.Tokar	M. Krutský
19	13.1.2016	Strana 3	L. Holub	L. Holub
20	06.10.2016	Page 3, 7, 11, 12, 13, 21	M.K., I.A	M. Krutský
21	27.1.2017	Revize verzí standardů v celém dokumentu	M.K., I.A.	M. Krutský
22	2.1.2018	Strana 4, 8	L.Turza	M. Krutský
23	1.4.2018	GMP+ str. 4,7,18	K.Macháčková	M. Krutský
24	10.05.2018	Strana 3,6,13,15,22,	M.Krutský	M.Krutský
25	9.11.2018	Změny vyznačeny barevně	L. Holub	L. Holub
26	15.11.2018	Změny vyznačeny barevně str. 4, 8	Ř. Prihara	L. Holub
27	28.4.2020	SJPK – aktualizace strany 6, 24	L.Turza	L.Holub
28	23.6.2020	SJPK – aktualizace strany 24	L.Turza	L.Holub
29	23.6.2020	SJPK – aktualizace strany 24	L.Turza	L.Holub
30	07/10/2020	Vložení „Osvědčení“ – str. 19, 20	Ř. Prihara	L. Holub
31	15/10/2020	Odstanění - posuzování „Her a Hraček“, diagram posuzování „Hmotných produktů“ podle SM str. 15	Ř. Prihara	L. Holub

LL-C (Certification)[®]

32	08.12.2020	FSSC 22000 and GMP+ FSA requirements	I. Angelovski	L. Holub
33	18.12.2020	FSSC 22000 Quality	I. Angelovski	L. Holub
34	8 march 2021	added procedure SPVD	L. Turza	L. Holub
35	10 march 2021	FSSC 22000 version 5.1 requirements	I. Angelovski	L. Holub
36	10 march 2021	(:2007 CL1 až CL4, :2020 CL1 až CL3)	Ř. Prihara	L. Holub
37	9 april 2021	Surveillance audit length ISO 22301	L. Nejedla	L. Holub
38	20 april 2021	Surveillance audit length, p. 20	L. Nejedla	L. Holub
39	11 november 2021	Corrections	L. Holub	L. Holub
40	25 february 2022	EN CZK versions corrections	L. Nejedla	L. Holub
41	4/4/2022	Changes visible in other color	L. Holub	L. Holub
42	16/06/2022	Changes visible in this colour p. 25_26 +12	L. Nejedla	L. Holub



Ing. Lukáš Holub
Vedoucí CO
21/11/2022