

LL-C (Certification)[®]



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

(Rule-03)



Revision No. 23 from 5 June 2020

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List revisions and motivations

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20	15.7.2017	Page 17	J.Dynybyl, J.Tomas	M.Krutský
21	4.8.2017	Pages 9, 10 and 11	L.Havlikova	M.Krutsky
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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, 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



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Safety Management Systems as per ISO 22000 and FSSC 22000) with the requirements of the HACCP and the and IT Service Management Systems as per ISO 20000-1, both in production and services companies.

LL-C provides certification of products according to EN ISO 3834, EN 15085-2, EN 17660-1, EN 17660-2, EN 14554-1, EN 14554-2 and ISO 22716 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, Medical Devices and Machinery Devices) in the scope of its accreditation and in conformity with ISO/IEC 17065.

Legal status of the organization is a limited liability company with 100% foreign investments. 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, section C inset 97630 IN 271 18 339. 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 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:

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- 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, MPA 50-01-07, ČSN EN ISO 19011:2012
- 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.

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 MPA 50-01-07 of Czech accreditation institute)

EN ISO 19011 - Guidelines for Auditing of Management Systems



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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 9001:2015. Out of this standard, quality management system must meet the expectations of the relevant field and customers.

Environmental Management Systems

For certification of environmental management systems is used standard ISO 14001:2015. 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) which that more integrated system of feedback and process management, and compatibility with the quality.

Occupational Health & Safety Management Systems

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.

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, EN 17660-1, EN 17660-2, EN 14554-1, EN 14554-2 and ISO 22716

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

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).

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.

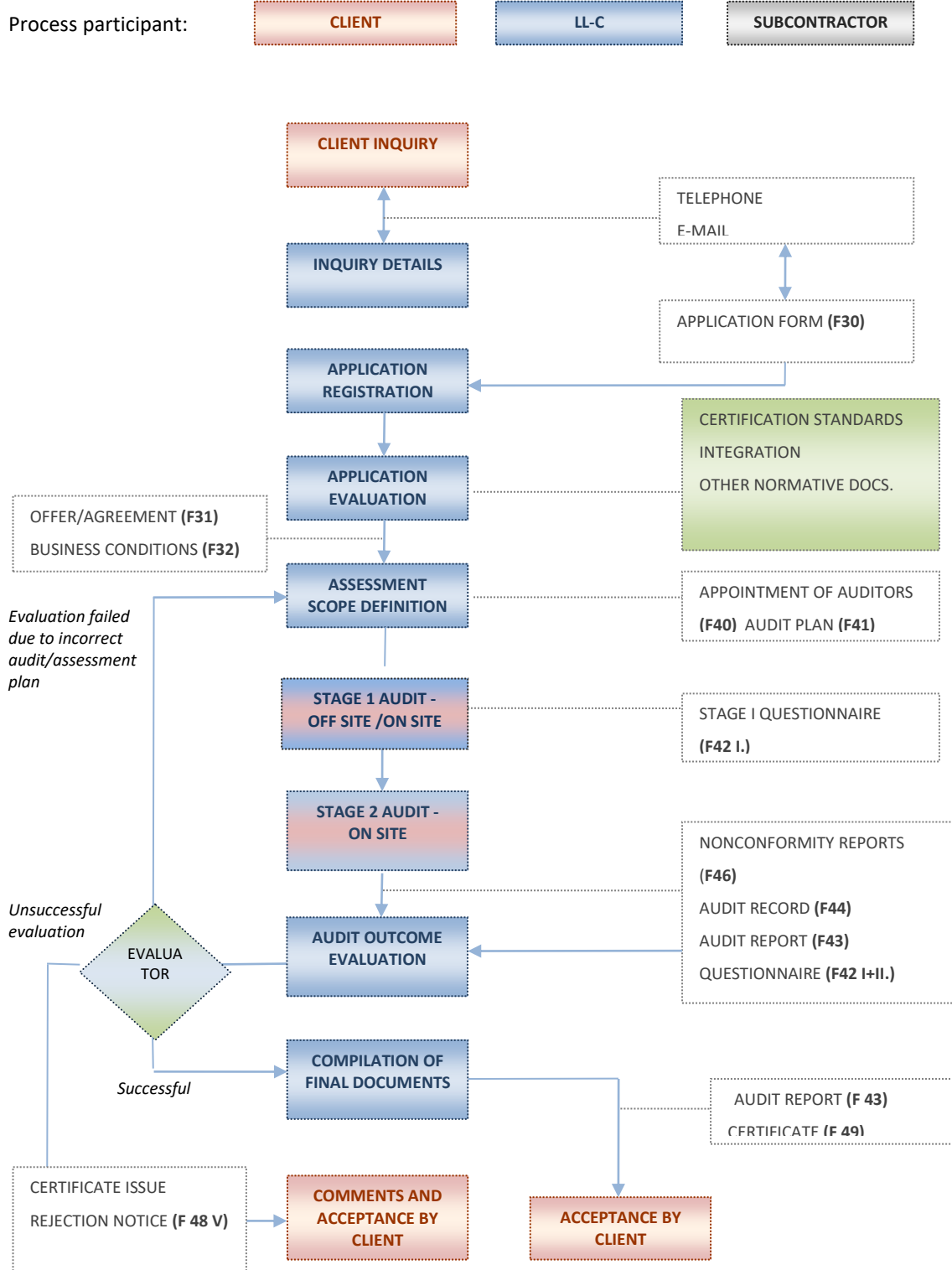
Software for MDD

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.

V. Certification processes

A) Process of Management Systems Certification

Certification process diagram



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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



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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 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. 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.

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;
- d) The scope of the MS management system is to be confirmed by

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- client's site
 - processes and equipment
 - levels of controls (especially of multisite clients)
 - statutory and regulatory requirements;
- e) Review of allocation of resources for 2nd stage and discussion with client details for 2nd stage;
- f) 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.

CAAT-RAT / ICT method (methods of remote assessment and their approaches not only in times of pandemic crisis COVID 19)

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

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.

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

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- 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.

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

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



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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

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 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 ad 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, 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. 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.

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.

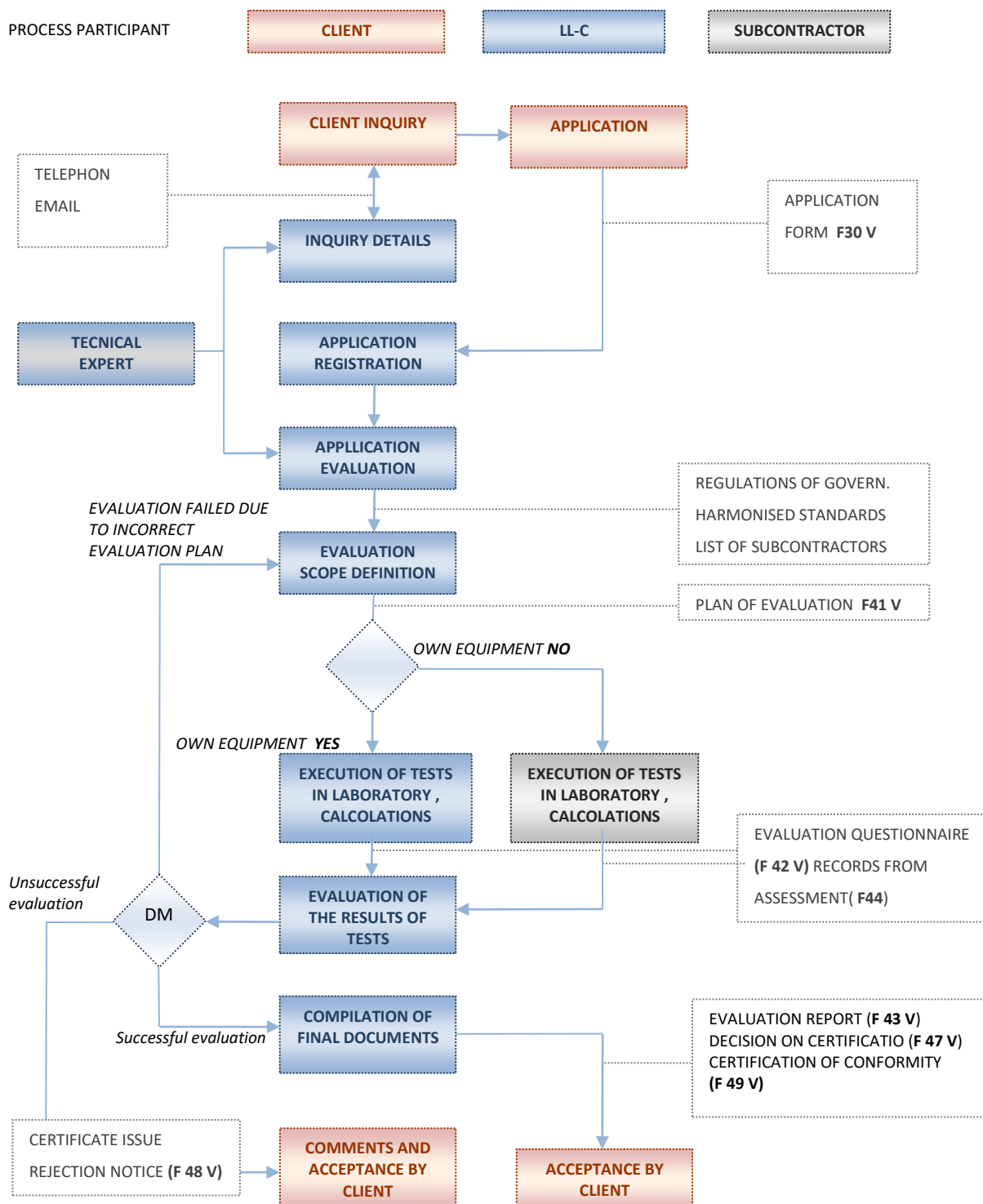
If the surveillance audit findings show that the client's management system doesn't fulfil the requirement of the standard the client gets the possibility to make corrective actions in determinate date. LL-C verifies and decides if the corrective actions are sufficient for maintenance of certification.

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, activities or documentation must be supplied at least 14 days before starting audit.

B) Process of Product Certification

Certification process diagram – certification of product, process or service*



*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).

The documentation at the stage of application for certification must adequately define the organizational structure 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

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- 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 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



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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

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 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 and marks

Use of the LL-C logos and marks is regulated under the terms of Business Conditions - F32. Certified subject must comply with the terms.

Maintenance of certification

Surveillance and remote surveillance audits



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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;
- d) Effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system (s);
- e) Progress of planned activities aimed at continual improvement;
- f) Continuing operational control;
- g) Review of any changes;
- h) 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.

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 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).



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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.

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:

- 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.

VII. Responsibility of Certification Body



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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 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.



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Certification Publications

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

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).

VIII. 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

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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
- In case of substantial large changes in the documentation.



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

IX. 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.

X. 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.

XI. 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.