



Rules for LNE Certification of Management Systems

Application date: June 17th, 2019

Rev. 040419

RULES FOR LNE CERTIFICATION OF MANAGEMENT SYSTEMS

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LNE CERTIFICATION RULES FOR MANAGEMENT SYSTEMS

1. PURPOSE

The present rules aim at introducing and defining the certification procedure for management systems for the purpose of LNE issuing a certificate attesting that a management system complies with the system-related standard which is defined by contract.

The rules specify the different stages of certification as well as the related actions and participating parties. They lay down the commitments of the entity applying for LNE certification or the entity holding the certificate issued by LNE as well as LNE's obligations relating to its certification activity.

2. SCOPE

2.1. Management systems

The management system certification procedure applies to the following management systems:

- Quality management system as defined in standard ISO 9001
- Environmental management system as defined in standard ISO 14001
- Health and safety at work management system as defined in standard ISO 45001 or OHAS 18001
- Information technology management system as defined in
 - standard ISO 27001, information security management systems
 - Health data hosting (HDS) certification standard

2.2. Stakeholders - Outsourcing

The management system certification procedure is applicable to management systems evaluated by LNE and its subcontractor, GMED, a 100% subsidiary of LNE.

LNE, as part of its certification activities according to ISO 17021-1 standard to assess the conformity of quality management systems, entrusts LNE ISO 9001 certification process for companies operating in the field of health and medical devices to GMED. As the owner of the LNE ISO 9001 mark, the LNE shall take responsibility for the outsourced activity within the meaning of Article 7.5.3 of ISO 17021 and all the rules described below apply.

The LNE certificate is granted to an entity that has a legal status, hereinafter referred to as company or applicant, identified within the framework of a given activity carried out on one or more sites determined within the framework of a same management system.

The type and the field of activity covered by the entity's application for certification should be clearly specified.

3. DEFINITION OF THE DIFFERENT STAGES OF THE CERTIFICATION PROCEDURE

Certification process is carried out on the basis of requirements of :

- ISO 17021-1:2015 standard – “Conformity assessment – Requirements for bodies providing audit and certification of management systems and related documents
- ISO 27006 for ISO 27001 certification
- ISO 27006 and HDS accreditation standard

The certification procedure is made up of 6 the different stages listed below:

- Preliminary stage;
- Application for certification;
- Initial certification audit;
- Certification decision;
- Surveillance of the entity;
- Certification renewal.

The certification process is described in the diagram appended to this document.

The purpose of audits is :

- to ensure the audited management system is compliant with the reference standard,
- to assess the management system effectiveness
- to identify areas for improvement of the management system.

Provisions made within the framework of an application for extension of certification may also be examined during surveillance audits.

A certification renewal audit is performed before the certification period runs out with an overall assessment of the entity's management system.

For each audit, the entity is informed of the audit team composition and may disapprove of the proposed auditors by specifying the reasons, resulting in a new proposal.

An audit plan is established and submitted entity for approval 10 working days before the audit. The plan is drawn up in accordance with ISO 17021-1.

Each on-site audit includes:

- An opening meeting with the entity management aimed at confirming the scope of certification and specify the audit plan;
- An assessment of compliance of the management system with the specified standard(s) and of its effectiveness;
- A closing meeting during which the lead auditor delivers his/her conclusions.

4. DESCRIPTION OF THE CERTIFICATION STAGES

4.1. Preliminary stage

When it first makes contact with the entity, LNE or its subcontractor, provides it with all information relating to the certification procedure and with a questionnaire to be filled in by the entity.

This questionnaire should allow:

- Identification of the entity, the persons to contact and its activities;
- Definition of the scope of the application for certification;
- Information retrieval on the management system and related documentation.

LNE or its subcontractor analyses the questionnaire and may suggest a diagnosis audit or pre-audit to better appreciate the extent to which the management system is developed. This preliminary provision of service is optional and is not a part of the certification process.

Following this first contact, the entity receives a certification offer which contains all the information required for a formal application for certification. The offer is based on the audit programme for the full certification cycle and takes into account the information provided by the Company. This audit programme can be modified at a later stage on the basis of changes made to the entity or to the certification scope, further to the results of audits or to modification of certification standards.

4.2. Application for certification

The application is made on the basis on the standard documents that the entity received and results in a contract being drawn up. This contract lists the applicant's and LNE's obligations and commitments. The scope of the application for certification is specified in the contract.

Upon signature of the contract, the company undertakes to apply these rules, which have a contractual value.

In support of its application, the entity provides all documents relevant to the assessment of the management system against the specified standard.

Documents should include at least:

- The handbook of the system concerned, when appropriate;
- A complete list of the system procedures or list of the documented information;
- A list of related products and services covered by the management system to be certified;
- Any other relevant document depending on the certification standard(s) requested.

LNE or its subcontractor processes the application and if admissible, schedules the initial certification audit with the applicant.

4.3. Initial certification audit

4.3.1. General points

The audit duration and the number of auditors are set by LNE or its subcontractor according to the size and the complexity of the organisation, the selected standard(s) and of LNE or its subcontractor's possible knowledge with the management system set up within the framework of other certification processes (product certification, regulatory certification, BRC/IOP certification).

When the entity is already an LNE certificate holder, for all or part of the field of activity concerned, the certification audit may be conducted jointly with an audit relating to the certificate issued and it takes elements already audited within that context into account.

The initial certification audit is conducted in two stages:

4.3.2. Stage 1

The first stage of the initial certification audit aims at ensuring that the entity fully understands the requirements of the applicable standards, identifying and collecting information relating to the scope of the management system, to the sites concerned, the regulatory and legal aspects that the entity should comply with. It aims at assessing the preparedness of the entity for the second stage, at verifying that the internal audits and the management review are being planned and performed, and at confirming the procedure defined for conducting the stage 2 audit.

This audit consists of a review of the documentation submitted by the entity liaising with the member of staff appointed by the latter, and of an on-site visit. In some duly justified circumstances, LNE or its subcontractor can decide to carry a remote audit using technical means such as teleconference or video conference. (ex: large distance of the site, entity already known by LNE or its subcontractor).

The results of the stage 1 audit are compiled into a report that is submitted to the entity. This report gives details on any identified areas of concern that could be considered as a non conformity during the stage 2 audit.

The results of stage 1 may lead to the postponement or cancellation of stage 2.

If significant changes affecting the management system take place, it may be necessary all or part of stage 1.

If need be, the arrangements for conducting the stage 2 audit may be modified in agreement with the entity.

4.3.3. Stage 2

The audit is made up of an assessment of the compliance of the management system operated by the entity with the standard(s) specified, an assessment of its implementation and its effectiveness.

This audit is performed on site in accordance with the procedure defined by standard ISO 17021-1, by an auditor or an audit team qualified and appointed by LNE. Auditors are qualified in conformity with the criteria set forth in ISO 17021-1 and the qualification criteria defined by LNE or its subcontractor.

The audit report is drawn up by the lead auditor and points out:

- Significant elements of the management system contributing to inspiring confidence in the entity achieving compliance with the baseline reference(s);
- Non conformities and relevant remarks with respect to the baseline reference(s);
- Areas or opportunities for improvement of the management system.

Non-conformities are classified according to a rule defined by LNE in its documentation. They must be the subject of correction and corrective actions suggested by the entity. Insomuch as they put the system's effectiveness to achieve the intended results or the compliance of the delivered product or service into question, they are identified as major and must give rise to correction and corrective actions duly specified and documented by the entity so as to verify their implementation before any certification decision is made.

Within 15 working days from the last day of the audit, the entity communicates to the lead auditor its possible comments, the causes analysis, the corrections and corrective actions that it decides to take further to the non conformities raised.

The audit report is analysed by the LNE or its subcontractor appointed representative and submitted to the LNE internal reading committee for an opinion and recommendations.

The committee sets out to examine the audit report. Depending on the nature and the seriousness of the non conformities identified and the correction and corrective actions suggested by the entity, it issues one or more of the following recommendations:

- Request for further information;
- Request for corrective actions with or without additional documentation assessment;
- Request for corrective actions with or without additional audit;
- Granting of certification, with or without observations.

These recommendations must be based on elements from the audit report or LNE certification rules.

The additional documentation assessment and the additional audit aim at verifying the implementation of the proposed corrections and corrective actions.

Major non conformities must be verified within 6 months starting on the last day of the second stage audit. If this deadline cannot be met, a new second stage audit is conducted according to the above-mentioned provisions.

4.4. Certification decision

On the basis of these recommendations, LNE decides to grant or not certification and informs the applicant of its decision.

The certification decision is made by LNE's General Director or his deputy.

The applicant is informed of the decision and if necessary a certificate is issued.

The certificate is recorded. LNE transmits all information relating to the status and content of the certificate and can publish the certificate.

The certificate is renewed automatically every year. On expiry date; it is renewed on the basis of provisions defined in sections 4.5 and 4.6.

It lists at least the following:

- Entity identification;
- The location(s) affected;
- The certification referential;
- The activity field covered by certification;
- The certificate validity (3 years for a normal cycle).

4.5. Entity quality surveillance

The certificate is maintained, on one hand, on the basis of commitments made by the entity during the application and on the other, the observations made during a surveillance audit occurring at least once a year.

If significant changes have occurred, the verifications concerning the maintenance of the management system can be carried out as part of additional audits.

4.5.1. Surveillance audit

The date of the first surveillance audit after initial certification is set within 12 months after the date of the certification decision.

If the entity holds a regulatory certificate or a product or service certificate managed by LNE or its subcontractor, the audit performed with respect to this certification may be conducted jointly with the surveillance audit.

The surveillance audit, the drafting of the report and the entity's answer to possible nonconformities during the audit take place in the same conditions as the stage 2 audit.

Within the framework of the entity surveillance, LNE decides whether to carry out surveillance audits or additional audits and on the provisions aimed at ensuring that the compliance of the management system is maintained:

- Request for corrective actions;
- Additional audit;
- Submission of the report to the reading committee for opinion.

If a non conformity considered as a serious hinder to the effectiveness of the audited management system or as jeopardising the expected product compliance is identified during one of these audits, LNE or its subcontractor submits the report to the reading committee for examination and a subsequent opinion on a suspension for a limited duration or a withdrawal decision.

In the transition period, LNE may take any conservatory measure that may be needed relating to the certificate validity or the request for corrective actions.

An application for extension of the certificate scope may be assessed during the follow-up audit. The audit duration is adjusted accordingly. Depending on the content of the application for extension, a step 1 audit may be required. (see 4.3.2)

4.5.2. Suspending, Withdrawing, Reducing the scope of certification

Reasons for withdrawing, suspending, or narrowing the scope of a certificate by LNE are as follows:

- Non compliance with contract requirements,
- Management system not compliant with requirements,
- Refusal of the holder to undergo a surveillance audit within the timeframe set by LNE or its subcontractor,
- Failure of holder to honour its financial commitments,
- Request for a cancellation of certification by the entity

LNE then formally notifies the holder of the suspension, reduction of scope or withdrawal by recorded delivery letter, indicating, in the first case, the terms and conditions of the lifting of the suspension, in particular the corrective measures to be taken and the suspension time established by LNE.

LNE or its subcontractor undertakes the verifications necessary to restore the certification. Where applicable, suspension is lifted and certification is back into force and the holder is notified.

Otherwise, LNE proceeds to withdraw or reduce the scope of the certification.

In the last case, provisions related to the use of the certification mark and certification reference mentioned in §8 must be implemented by the entity.

4.6. Certificate renewal

Before the certificate expires, LNE or its subcontractor carries out a renewal audit.

The renewal audit aims at confirming the management system as a whole is still compliant and effective, as well as continuously operating within the scope of certification.

In case of major modifications of the management systems or affecting the entity a step 1 audit (see 4.3.2) may be necessary.

The renewal audit must be completed at least 3 months before the expiry date.

The results of the renewal audit are examined following the same provisions as for an initial certification audit.

Decision to renew the certificate is made following the same procedure. It takes into account the results of the renewal audit, the entity's evolution for the whole certification period as well as possible complaints registered against the certified entity.

In the event of a major nonconformity being raised during a renewal audit, corrections and corrective actions should be implemented by the applicant within the time frame set by LNE or its subcontractor, which must verify the implementation of corrections and corrective actions before the validity of the certification expires.

In the event of a nonconformity and on recommendation of the reading committee, LNE makes one of the following decisions:

- Refusal of renewal of the certificate;
- Request for corrective actions within a deadline and verification of their implementation via document assessment;
- Request for corrective actions within a deadline and an additional audit.

When the renewal audit or the verification related to the implementation of corrections and corrective actions for major nonconformities cannot be completed before the expiry date of the certification, the certificate is not renewed. LNE may restore the certification within 6 months from the end of validity of the certificate if and only if the above-mentioned actions are completed and result in a favourable outcome. After this period, a new stage 2 audit must be conducted. During the period where the entity has no certification, it must give up advertising or making reference to certification.

Upon renewal of the certificate, the date of expiry is based on the date of expiry of the previous certificate.

5. APPEAL

The applicant or the certificate holder may appeal against any of LNE's decisions for activities related to the certification of management systems.

The appeal has not a suspensive effect. The reasons for appealing must be provided. The appeal should be notified by registered post with acknowledgement of receipt within 15 days of receipt of the notification by the company.

It is processed by LNE within 30 days of reception and is examined by the reading committee whenever it relates to the certification decision or the certification rules. The LNE notifies the entity of its decision within 30 days.

In case the appeal is maintained after being investigated and submitted to the reading committee, it is passed on to LNE's certification committee as defined in article 7 which, after examination, offers its conclusions to LNE general director.

Final LNE decision is notified to the appealing entity.

Any further appeal may be submitted to the competent authority within the Ministry in charge of industry or is passed on to the competent court.

6. COMPLAINTS HANDLING

Any complaint received by LNE or its subcontractor is examined by LNE or its subcontractor to ensure and confirm the complaint relates to activities certified by LNE.

When it affects an entity holding certification, LNE or its subcontractor informs the entity concerned to proceed to examine the complaint.

The entity concerned should then inform LNE or its subcontractor of the outcome and keep records relating to the complaint and the measures taken to solve it at LNE or its subcontractor's disposal.

Verification that the announced actions have been implemented is carried out during the following audit at the latest.

When there is significant doubt on the continued effectiveness of the management system, LNE or its subcontractor can carry out an additional audit. This audit can be unannounced (without a prior notice to the entity).

Within the framework of the entity surveillance, LNE or its subcontractor examines the records relating to complaints and checks that appropriate corrective actions have been initiated.

7. PARTICIPANTS AND RESPONSIBILITIES WITHIN THE FRAMEWORK OF THE CERTIFICATION PROCESS

LNE Board of Directors:

- Defines the certification policy;
- Monitors certification activity finances;
- Delegates to LNE's Managing Director decisions relating to the operation of certification and the setting up of certification committees as well as the appointment of their members;
- Delegates to the certification committee the monitoring of the certification policy implementation on the basis of an annual report presented by LNE's Managing Director or his/her deputy.

The General Director, on behalf of the Board of Directors:

- Decides on the creation of the certification and safeguarding impartiality committee aimed at facilitating the consultation of parties involved in certification ; he also designates the committee members;
- Delegates to the committee the monitoring of LNE's compliance with impartiality rules;
- Makes certification-related decisions (granting, renewal and withdrawal), and relies for this purpose on recommendations issued by the internal reading committee or the certification committee opinion if necessary;
- Plans out the certification body policy and the responsibilities that follow;
- Appoints the staff in charge of certification operations.

The certification and safeguarding impartiality committee is created by the Managing Director and is made up of members representative of interests involved in certification. The certification committee:

- Approves the present certification rules;
- Issues recommendations on ways to apply these rules;
- Investigates appeals against certification-related decisions after analysis by the reading committee and suggests courses of actions;
- Ensures LNE complies with impartiality rules.

This committee may be joint with the GMED committee

The reading committees are committees to help the decision-making. They are internal to LNE or its subcontractor and they are made up of staff qualified for the targeted certification activities. The reading committees:

- Examine audit reports, give an opinion and issue recommendations relating to actions to be taken and decisions to grant, renew or withdraw certification.
- Investigate appeals against LNE's decisions and forward the elements on to the certification committee for a review and a proposal on decisions to make.

8. CERTIFICATION MARK AND REFERENCE TO LNE CERTIFICATION

The certification mark that identifies certification of the management system by LNE is displayed hereafter:



The LNE mark is registered with the INPI with specific rules covering the use of the LNE certification mark for management systems.

Its use is strictly reserved to LNE within the framework of corporate publicity and to the certificate holder that has received the corresponding notification according to terms and conditions defined by specific rules.

When testing or calibration or inspection activities are covered by the certification, reports or certificates issued by the entity as part of its activities are considered as products and, as such, the certification mark must be not applied on these documents.

A reference to the certification can be made on the product packaging or in the accompanying document if and only if:

- The product concerned is covered by the scope of the certification held by the entity;
- The reference includes:
 - the name and address of the certified site,
 - the type of management system, the certification standard and its year
 - the name of LNE, entity issuing the certification.
- The statement does not imply that the product, service or process is certified by LNE.

When referring to the certification, the entity must meet the following requirements:

- a) comply with LNE's requirements when making reference to its certification status in communication media, such as websites, brochures or advertising and other documents;
- b) do not make or permit any misleading statements regarding its certification;
- c) do not use or permit the use of a certification document, in whole or in part in a misleading manner;
- d) upon withdrawal of its certification, cease all advertising which refers to its certified status;
- e) modify any advertisement if the scope of certification is reduced;
- f) do not allow any reference to the certification of its management system which would imply that a product, service or process is certified by the LNE;
- g) do not imply that the certification applies to activities and sites that are not covered by the certification scope;
- h) do not use its certification in such a manner that would bring LNE's reputation and / or the certification system into disrepute and thus compromise public confidence.

Anyone who makes abusive use of this mark or abusively refers to LNE certification shall be prosecuted in application of current laws relating to misleading advertising and intellectual property.

These rules are reviewed on a yearly basis. They may be revised at LNE's suggestion or on request coming from members of the certification committee. Modifications must be approved by the committee.

The present revision of management system certification rules was approved by the certification and safeguarding impartiality committee on April 4th, 2019.

Annex Rules for LNE certification of Management Systems

MANAGEMENT SYSTEM CERTIFICATION PROCESS

