

Statutory quality system approval for measuring instrument manufacturers and LNE ISO 9001 quality management system certification

These guidelines are intended for companies who wish to apply to LNE for:

- **Statutory quality system approval** to manufacture measuring instruments covered by the provisions of French decree no. 2001-387 (3 May 2001), European Directive 2014/31/EU modified (Non-Automatic Weighing Instruments) or European Directive 2004/22/EC (Measuring Instruments).



or
CE

Once a company has obtained statutory approval for its activities for controlled measuring instruments, it may affix French national marking to measuring instruments covered by French regulations or CE marking to measuring instruments covered by the new-approach Directives.

At the same time companies may apply for:

- **LNE ISO 9001:2015 quality management system certification** covering all company activities.



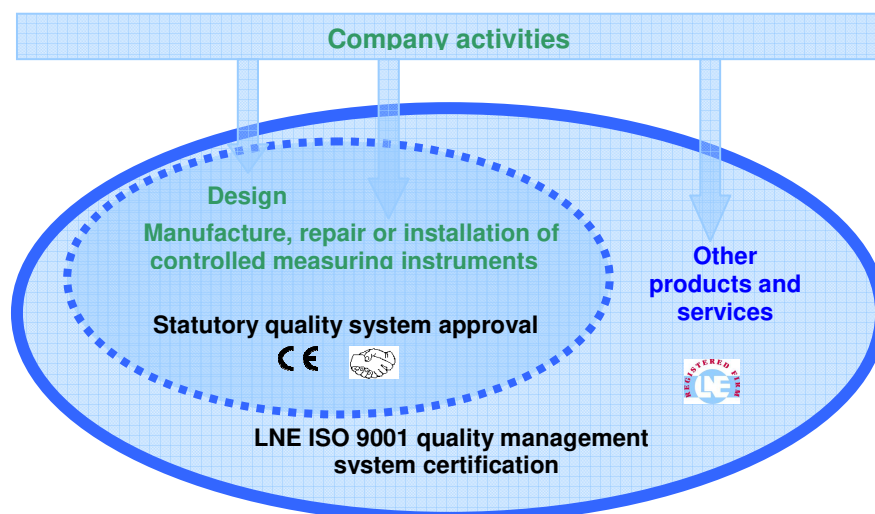
With this certification a company may use the *registered firm LNE* mark.

If you apply for both statutory approval (requiring quality system compliance with ISO 9001:2000) and LNE ISO 9001:2015 quality management system certification, you will enhance customer perception of all of your company's activities, whether regulated or otherwise.

In addition, you may apply for ISO 14001:2015 certification for your environmental management system.

ISO 9001 and ISO 14001 certifications are conducted on the basis of Rules for LNE company certification ISO 14001-ISO 9001.

- **Complementarity of quality system approval and quality management system certification**

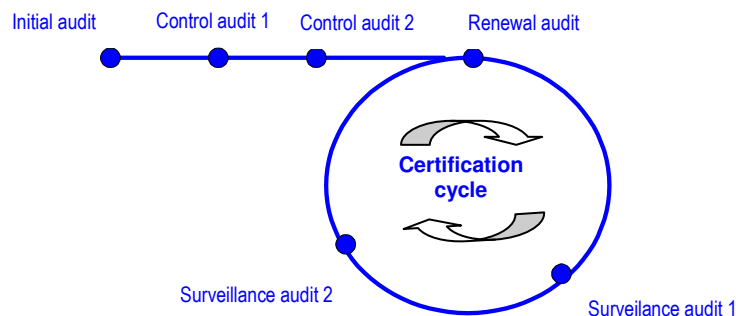


- **Cycle for quality system approval and quality management system certification**

Both statutory quality system approval and LNE ISO 9001 quality management system certification are covered in the one cycle. The cycle comprises:

- An initial certification audit conducted in two stages,
- Two control audits at yearly intervals
- A renewal audit at the end of the third year.

The cycle* is then repeated every three years:



* Under the statutory approval procedure, monitoring of your quality system also involves possible unscheduled visits by LNE auditors.

- **How to apply for quality system approval or QMS certification**

- ① Complete all sections of the **application form** and return it to LNE with the required documents.
- ② After examining your application LNE will send you an **approval contract** (and a **certification contract** if requested) corresponding to your requirements and a **quotation** for the services to be performed.
- ③ To accept LNE's proposal, return the contract(s) with an order for the services.
- ④ LNE will register your order and begin the certification cycle according to the procedure detailed in **annex 1**.

LNE determines the audit time according to the rules published by the International Accreditation Forum (IAF - www.iaf.nu). The time required for technical and regulatory assessment is taken into account.

If your quality system is certified by a body accredited by French accreditation committee COFRAC or by a signatory of the EA agreement, LNE takes into account this certification and reduces audit time.

- **Measuring instruments covered by French regulation**

A company that manufactures controlled measuring instruments may apply for quality system approval according to a statutory reference document only if it possesses a type examination certificate covering the instruments concerned.

LNE assesses the conformity of your quality system according to the Decision of 29 October 2004 setting out detailed requirements applicable to the quality assurance systems of companies that manufacture controlled measuring instruments. The Decision may be consulted on our website www.lne.fr page Legal metrology/ Downloadable documents.

The LNE audit comprises:

- On-site assessment of your quality system according to ISO 9001:2000 and
- On-site technical and regulatory assessment of quality system application, through observation of the conformity declaration procedure for a measuring instrument.

- **Measuring instruments covered by 2014/32/EU Directive**

A company that manufactures controlled measuring instruments may apply for quality system approval according to a statutory reference document only if it possesses an EC type examination certificate.

LNE assesses the conformity of your quality system according to the Directive requirements and WELMEC application guides or standard documents the company has chosen. They are available at www.welmec.org.

Annex 1

Procedure for statutory quality system approval and LNE ISO 9001 quality management system certification

