

Statutory quality system approval for
measuring instrument manufacturers
and
LNE ISO 9001:2000 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 90/384/EEC modified (Non-Automatic Weighing Instruments) or European Directive 2004/22/EC (Measuring Instruments).

Once a company has obtained statutory approval for its controlled activities, 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:

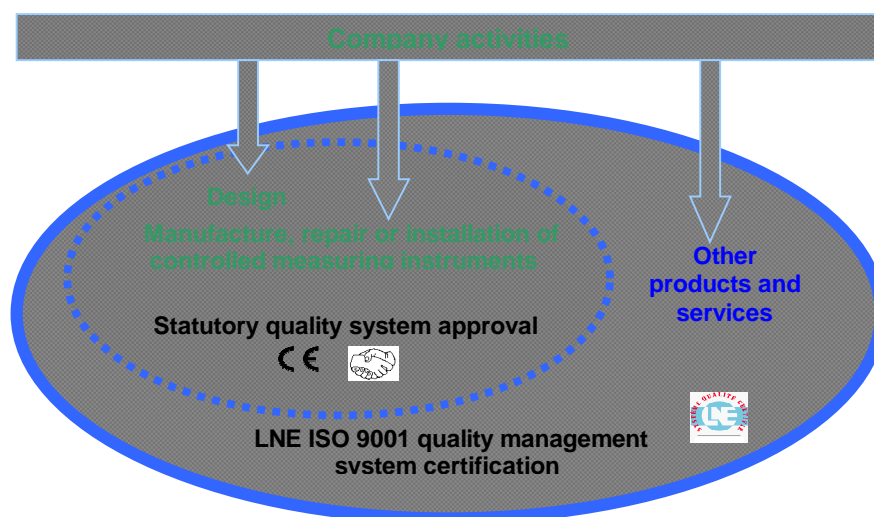
- **LNE ISO 9001:2000 quality management system certification** covering all company activities.

With this certification a company may use the *Entreprise Certifiée LNE ISO 9001:2000* mark.



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

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



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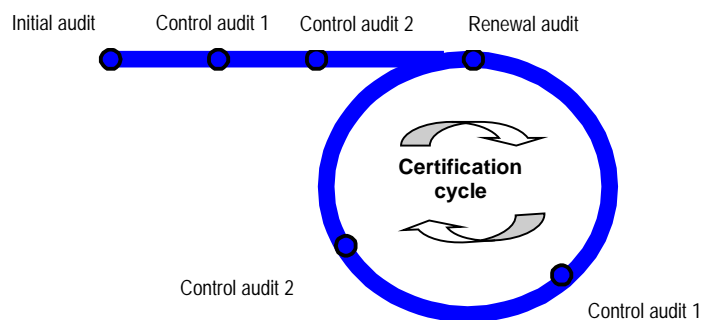
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- **Cycle for quality system approval and quality management system certification**

Both statutory quality system approval and LNE ISO 9001:2000 quality management system certification are covered in the one cycle. The cycle comprises:

- ? an initial audit
- ? 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**

- Complete all sections of the **application form 720 CIM 701** and return it to LNE with the required documents.
- , 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.
- f* To accept LNE's proposal, return the contract(s) with an order for the services.
- „ LNE will register your order and begin the certification cycle according to the procedure detailed in **annex 1**.

- **Statutory quality system approval by LNE**

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, an EC type examination certificate or a design examination certificate covering the instruments concerned.

LNE assesses the conformity of your quality system in one of two ways:

- ? If the reference document for your application is **French decree no. 2001-387 (3 May 2001)**, conformity is assessed 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: http://www.lne.fr/fr/metrologie/metrologie_legale/documentation_ligne.shtml.
- ? If the reference document for your application is a **new-approach Directive**, conformity is assessed according to the WELMEC application guides for the modules covering conformity assessment on the basis of quality assurance. They are available at www.welmec.org.

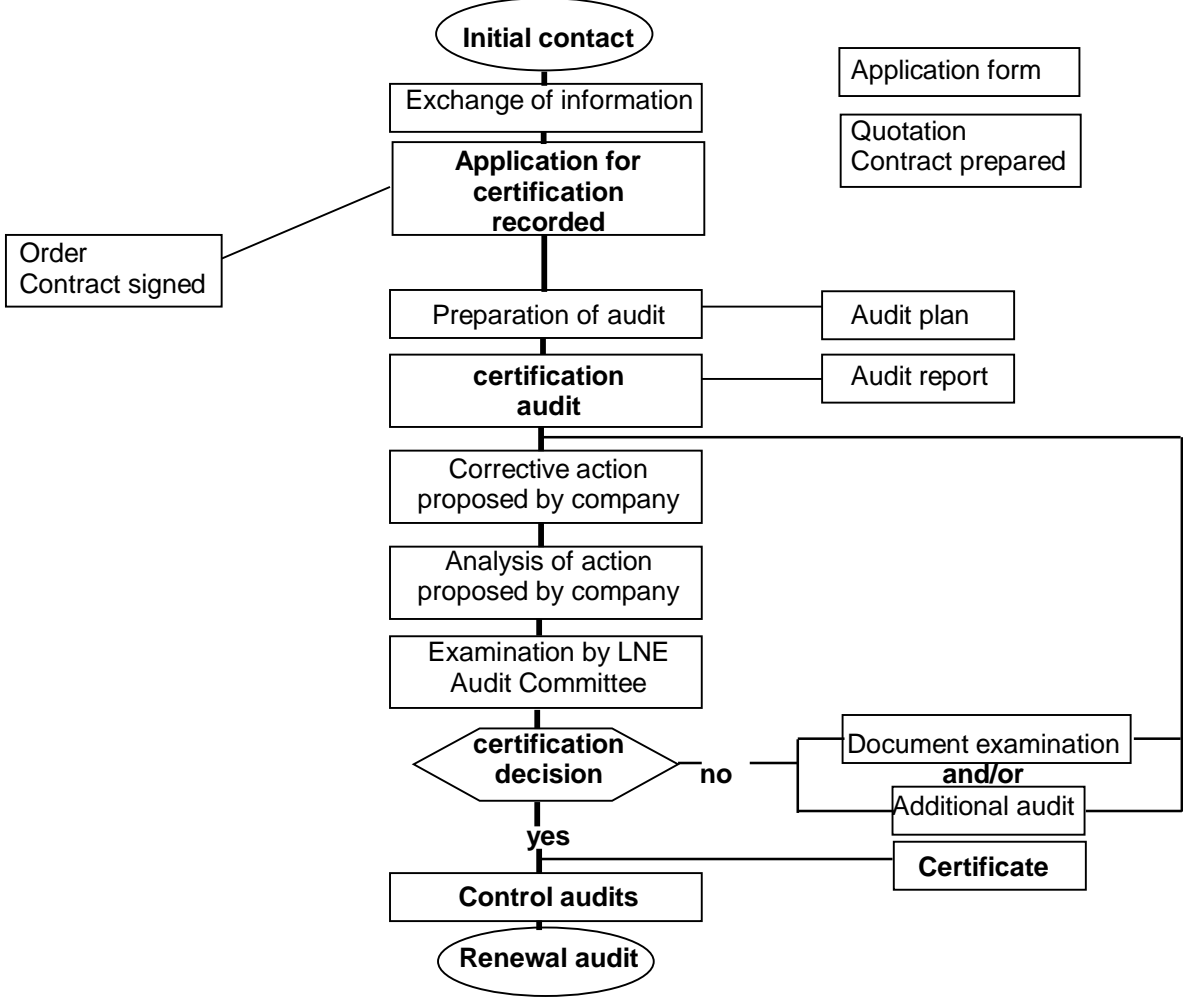
The LNE audit comprises:

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

LNE determines the length of its audits according to the rules contained in *Guidance on the Application of ISO/IEC Guide 62:1996 - General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems, Issue 3 (IAF GD 2:2003)*, published by the International Accreditation Forum (IAF). The time required for technical and regulatory assessment is taken into account.

If your quality system has already been certified by a body accredited by French accreditation committee COFRAC or by a signatory of the EA agreement, LNE takes this certification into account and reduces audit length according to ISO 9001:2000.

Annex 1
Procedure for statutory quality system approval and LNE ISO 9001:2000
quality management system certification



The procedure is the same for both statutory approval and QMS certification.