I - ORGANIZATION OF A QUALITY CERTIFICATION SYSTEM. CERTIFICATION BODIES, INSPECTION BODIES AND TEST LABORATORIES

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Certificacion is at present considered to be a basic instrument to improve the quality of a company´s products and services. in view of this consideration, each country´s Administration should undertake to see that adequate structures are provided in order to develop this activity, taking into special account the situation of the national industry and the Certification systems that have been developed in European and International fora.

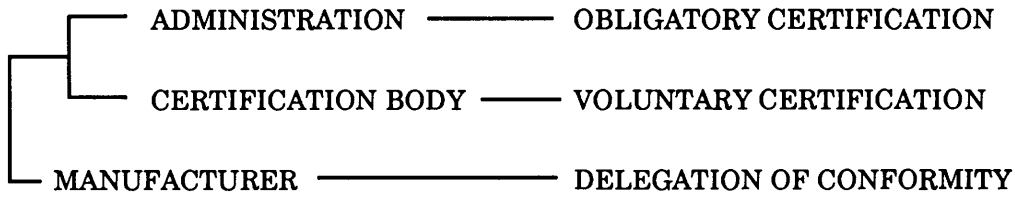
The process of Certification requires the application of one of two ways. The first of these is carried out via the Public Administration, which, by means of the prevailing legislation, calls for obligatory Certification. In some countries, this is called Homologation.

The other method is the development of voluntary Certification through those Certification Bodies recognized by the Administration, which in the majority of industrialized nations, are generally private organizations.

These two ways may coincide if the Administration establishes the appropiate legislative framework to recognize voluntary Certification as a testing ground for obligatory Certification.

There should be no doubt that this alternative is the most effective method to ensure that obligatory Certification not be used as a technical obstacle, but rather as a first step toward the development of voluntary Certification, which generally tends to be more demanding with regards to the parameters of quality.

An important aspect of conformity Certification is that of the person or body issuing the Certification. The following choices are possible:



The ISO defines self-certification as a process by which the manufacturer assumes the responsibility of stating when a product conforms to a certain standard. In such a case, the corresponding Certification Body has previously had to authorize the manufacturer's utilization of the name of the this process of self-certification. At the European level, the declaration of conformity is presently defined by the Certification issued by the manufacturer, but allowing, at the same time, for the intervention of a third body to carry out an additional stage of control; this is set out in the Directives governing the EEC'S new approach.

CERTIFICATION SYSTEMS

When a certain country decides to develop the process of Certification conforming to a given set of standards, the following must be kept in mind:

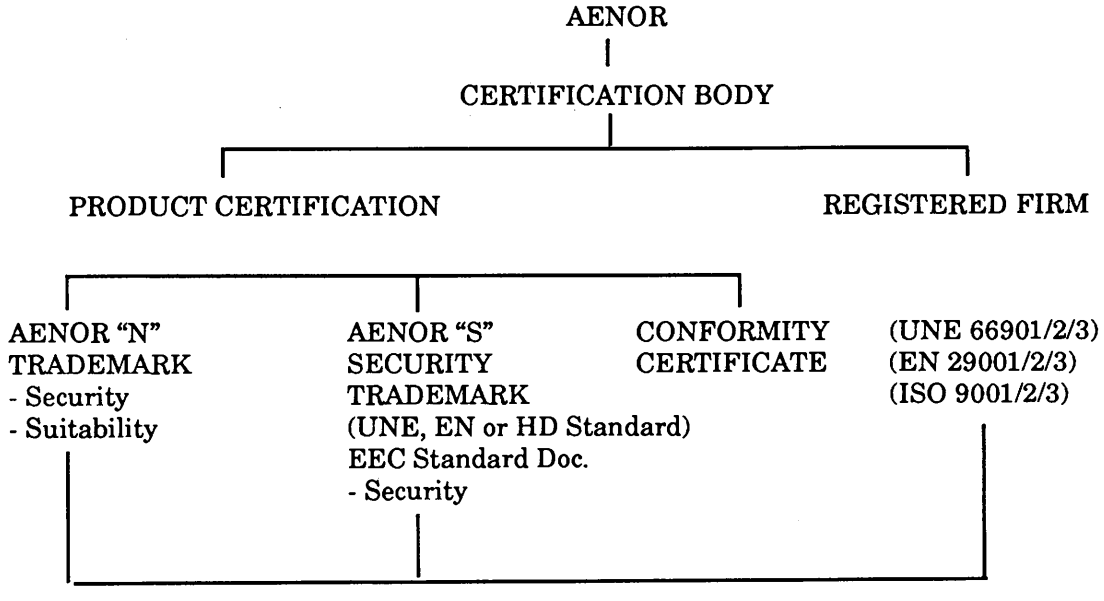
1. The needs of the National Industry

   - At the level of the domestic market
   - With regards to exportation

2. The technical capacity at the national level of:

   - The Certification Body
   - Testing laboratories
   - Inspection systems

In Spain, the need to restructure and strengthen Certification activity was recognized in 1986. With this objective in mind, AENOR was created in 1986 and since then the following Certification systems have been developed:



A) AENOR "N" Trademarks and the AENOR "S" Safety Trademarkconsist of:

1. Inspection: - of the manufacturer's own controls with regards to the product.
- of the quality assurance system, conforming to one of the 66901/2/3 standards.

2. Sample taking of the product during the inspection visit and the sending of these samples to an accredited laboratory.

3. Testing of the product in the laboratory.

4. Studying the Inspection and Testing reports.

5. The concession of the Trademark if the reports are positive. Withdrawing the Trademark if the reports are negative and preparing a modification proposal.

6. Monitoring of the product and the company in the market and in the production centre.

B) Conformity Certificates are issued when the concession of a Trademark is not possible.

The applicable Certification procedure is examined with respect to:

- Fulfilling a national or community regulation
- Exportation/Importation
- Verification of a manufacturer's lot
- Others (a single manufacturer, product etc.)

Possible procedures:

1. Testing of the prototype
2. Testing of the prototype and mass production control
3. Testing of the prototype and factory inspection (quality systems)
4. Testing of the prototype and factory inspection (quality systems and mass production control)

C) The Registered Firm test consists of the evaluation of the quality system of the company in accordance with the UNE Standards 66901/2/3 (equivalent to the ISO 9001/2/3). The procedure is as follows:

- Preliminary questionnaire. This is completed by the company and returned to AENOR. If it can be concluded from the questionnaire that the company does not have a functioning quality control system, it will be advised to seek consultation before continuing with the transaction.

- If the preliminary questionnaire indicates that the company does have a functioning quality control system, AENOR asks to inspect the company's Quality and Procedure Manual. If the examination of this Manual does not give rise to any problems, a meeting is held (a preliminary auditing) between AENOR and the company to develop the evaluation programme, where the following are laid forth:

- The company's quality system
- The selection of the ISO Standard and its concrete application with respect to the company
(The evaluation programme may be converted into a sectorial Regulation if so desired by the companies of the sector)
- The cost and monitoring of the company
- The technical standards or specifications by which the company functions
- The frequency and schedule of auditings
- If necessary, the changes that must be made to the relevant quality control standards

Auditory visits. A report must be made for AENOR. If it is negative, the company must correct the problems.

- If the inspection report is positive, a Registered Firm Certificate is issued.

- Annual inspection of the company´s quality assurance systems is carried out.

ELEMENTS OF THE CERTIFICATION PROCESS

The Certification Bodies may choose to exercice this function by means of an integral Certification system, or, in other words, implement their own testing laboratories and employ their own quality control inspectors and auditors in order to carry out the evaluation of a company´s quality system. A non-integral system may also be employed by which both activities are subcontracted out.

When this latter method is chosen, it becomes necessary for the Certification Body to be able to guarantee that both the testing carried out by the subcontracted laboratories as well as the audits realized by the subcontracted evaluation entities are of a standard sufficiently high to subsequently be worthy of the trademarks and certificates issued by the Certification Body.

A laboratory´s technical competence is presently demonstrated by means of the national accreditation systems for testing laboratories, which, in the case of Spain, is the Red Española de Laboratorios de Ensayo (RELE).

AENOR only employs laboratories which have previously been accredited by the RELE for the testing of products which are to be certified.

The accreditation process of these laboratories conforms to the European Standards EN 45.000. These tests may therefore be used in the signing of agreements for the recognition of AENOR Trademarks and Certificates with other EEC countries or at an international level.

The technical competence of the evaluation entities is demonstrated by estblishing a procedure for their recognition by the Certification Body, while at the same time carrying out the training and qualification of their auditors.

AENOR has established a procedure by which to qualify the auditors of these recognized entities. It should be pointed out that Conformity Certification has evolved over the course of the last few years to the extent that product inspectors have become fully fledged qualit system auditors. They must not only be familiar with the type of production but must also be experts in the auditing of quality control systems.

At present, there are several Certification procedures, such as that of the Registered Firm, for which the principale point of reference upon the signing of agreements of recognition of such procedures with other EEC countries and with EFTA is the qualification of the auditory personnel. Another aspect to take into account is that in order to help industries to introduce quality systems, there must exist the entities capable of assessing these systems; that is to say, there must be consulting bodies which are not necessarily at the same time auditing bodies. In this respect, a great effort must be made to compensate for the scant number of technicians trained in quality assessment in order to bring about the restructuring of quality systems required at present by industry.

CERTIFICATION AS CONSUMER PROTECTION

It is the responsibility of the Administration to work for an improved quality of life for its citizens, and this, among other activities, presupposes the improvement in the quality of products and services.

There are many parameters which affect dally life and a multitud of products and services we use which at times can cause us to suffer serious misfortune and problems.

Within this context, then, conformity certification according to certain standards is an efficient instrument to better the consumer's quality of life.

Certified products contribute to:

1. Offering the consumer greater confidence, since the products have been controlled by an independent body.

2. Fulfilling national standards which have been reached in agreement with all interested parties: the Administration, the consumers and users, and the manufacturers.

3. Maintaining an adquate quality level, since certification is a dynamic activity subject to periodic controls of both the certified product and company.

4. Implementing quality systems in the company, thus improving the quality of the products at the least possible cost to the consumer.

The Certification of a product is made known by passing the information on to the consumer. This process is simplified when the Certification is achieved by means of a conformity Trademark.

To introduce Certification into the market, it is necessary to:

- Spend both time and money to introduce the Trademark into the market by means of promotion campaings, television advertisements, specialized magazines, the press in general etc.

- Implement public purchases or obligatory performance standards. If the purchase of certified goods is given preference, thus marking a difference with non-certified goods, the manufacturer will be motivated to seek Certification for his/her product.

- Motivate the producer to:

a) Respond to consumer demand
b) Assume a legal responsibility at the point of sale. Distributors prefer to sell certified products because these offer greater confidence.

c) EEC Directive 85/375. Assume responsibility for defective products. This Directive refers to defects and damage, identifiable through standardization. The best way to demonstrate the fulfillment of the relevant standards is through Certification.

THE EUROPEAN SITUATION

Certification is an indispensable activity in the quest to raise and improve the quality of both products and companies. It is therefore used by the various national Administrations as a basic instrument in industrial quality policy.

At present, Certification is considered to be one of the basic elements in the achievement of the single market in 1992 by the European Economic Community member countries.

The process of Certification, or Community Evaluation, as it is more commnly known, requires for its development testing laboratories, inspection units and an adequate normative body.

With the new Community legislation, national Certification will go through a profound transformation as it evolves into European Certification, in which national application standards become European ones. This without doubt implies an extremely rapid development of this activity and the signing of recognition agreements with respect to Trademarks and Certificates among recognized Certification bodies of the various Member States.

This change in philosophy and the transformation of national Certification into European Certification presupposes, in the first place, the restructuring of the Certification bodies themselves, which, in order to be recognized, must adapt to be able to fulfill the EN 45000 Standards. This implies the implementation of quality systems as well as encouraging the participation of all parties involved, such as the consumers, manufacturers and the Administration, in the development of these activities - a very important consideration, given that not all Certification bodies at present functioning in Europe work in this way.

Secondly, it calls for the adaptation of the quality systems themselves at the national level to agreed-upon European levels, in which a trademark´s importance will depend upon the procedure set out by each Certification system created.

Taking into account this new approach to Certification, it will first be necessary for industry at the national level to apply an fixed Certification procedure.

In European fora, the best system will be negotiated and debated, and a consensus will be reached that will spell out the common rules that shall be appliedl These rules will have a summary importance, since they will govern the cost of Certification to the manufactuer and the organization itself of his /her production system; the number of controls that will be carried out; the standards that will be applied; whether quality systems will be introduced or not, etc. In other words, participation right from the beginning, to be able to have the option to negotiate, is essential, although it may later imply that the manufacturer and all his /her competitors in other EEc countries have to adapt to the standards agreed upon in the European forum.

Another important and beneficial aspect is that by means of the application of Certification systems an improvement in quality will certainly come about. Once applied, a study of the benefits obtained by the company with respect to the new organization should therefore be carried out.

It should no be forgotten that Certification is a dynamic activity that varies over time and which works to incorporate into the development of its systems the improvements in quality in the production systems that have been agreed upon and defined at the international level. Proof of this is the step being taken both at the European as well as the international level with respect to quality control techniques or quality management, now commonly refered to as quality assurance, based upon the European and international ISO 9001/2/3 standards.

This has given rises to a change from the simple conformity certificates with standards based upon standard testing, o the concession of trademarks based upon an inspection of the manufacturer´s quality system. In the very near future, this process will aso be comprised by a prior Registered Company test or a demonstration that the company is capable of making a product well, in addition to being able to prove that the product itself is good.

2) As we pointed out in the beginning, the satisfactory development of Certification presupposes a technical infrastructure at the national level which is capable of competing with the more developed ones in other European Economic Community countries. If there are no laboratories in Spain which can carry out the testing, other European laboratories will have to be used, which would hamper the efficiency and smoothness of the Certification process itself, as well as increase the cost and put the national industry in an inferior position with respect to its European competitors, for having to rely on other countries organizations.

The EEC Commission itself has declared, in its Global Planning In Certification and Testing, that only the most industrialized countries of Europe have the infraestructures with the technical capacity required for the functioning of the internal market in 1992.

3) Finally, it is important that we point out that Certification is never applied for by the manufacturer, unless the possessing of a trademark or certificate gives him/her some commercial advantage.

At the European level, it should be underscored that the majority of certified products in the market are a result of obligatory Certification or the Homologation of products. Once manufacturers find themselves obligated to control their products through Homologation, they apply to voluntary Certification bodies in order to benefit from the promotional advantages carried out of these bodies through their own, generally private, systems.

Obligatory and voluntary Certification are therefore intimately bound, and it is thus of great importance that the Administration has recognized this fact.

Introducing Certification to the market by means of conferring trademarks will take time and money. Only when it creates a notable difference in the market for both consumers and users will it become a basic tool for industry. From that point on, Certification can be used as a key instrument to raise the quality of the national industry. This support is vital in view of 1992, since the recognition of our trademark recognition agreements mong the certification bodies in the EEC.

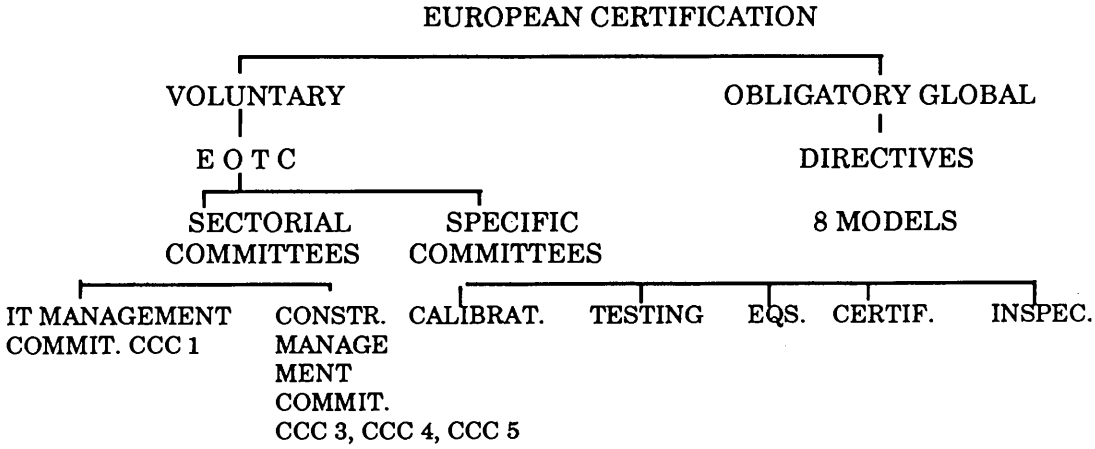
If the economic operators participating in Certification do not recognize the importance of obtaining Spanish Certification for industry, the signing of recognition agreeements will require even more negotiation and will relegate the national industry to a level inferior to that of its European partners.

At the European level, voluntary Certification is clearly differentiated from obligatory Certification. There presently exist two documents which outline the future development of Certification in Europe. These are; Approche Global (COM 89 -209 final - SYN 208) within the obligatory Certification context; and within that of voluntary Certification, the Memorandum released by CEN/CENELEC.

The first document specifies the Certification models which will be applied in all the new approach Community Directives. Those models which may be used will be defined for each product and the manufacturer will be left with the option to choose among the authorized models in order to demonstrate his/her product's conformity with the essential security requisites outlined in the Directives.

As to voluntary Certification, the CEN/CENELEC and the Commission together are developing a structure which will establish Sectorial Committees; these in turn will create Agreement Groups for each respective product in which will be negotiated the Trademark and Certificate recognition agreements. There will aso be Specific Committees of a horizontal nature which will also be Specific Committees of a horizonal nature which will work to harmonize and develop systems which subsequently will be used by the Sectorial Committees as the basis for the signing of these agreements.

The European structure upon which this activity will be developed will be denominated the EOTC (European Organization Testing and Certification).



There should be no doubt that, at the European level, Certification has undergone a considerable development since 1986, and that it is one of the "protagonists" in the achievement of the 1992 internal market, in which will participate 320 million consumers.

However, this development should not be considered as merely a matter of interest for Europeans. The evaluation of conformity standards is in itself a great support for industry in general and should continue to be developed in order to adapt to the necessities of future international markets.