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## Annex 1

### **THE INTERNATIONAL STANDARDIZATION ORGANIZATION (ISO) AND THE ISO 9000 FAMILY OF STANDARDS<sup>17</sup>**

The ISO elaborates international standards and guidelines taking into account the interests of users, suppliers, scientific communities and governments. These standards have a wide scope covering all fields, with the exception of the electric and electronic technology that depends of the IEC (International Electrotechnical Commission).

It also establishes standards and guidelines to evaluate conformity. ISO elaborates the requirements of products and systems certification, as well as the requirements for the accreditation of system, personnel, product certification agencies and the calibration and rehearsal laboratories accreditation through the Conformity Assessment Committee (CASCO).

Among the standards published by ISO, the most internationally known is the ISO 9000 family of standards. This group of standards describes the way to carry on quality management and the creation of the corresponding quality and continual improvement systems in a given organization.

In 1987, the first version of the ISO 9000 standards was published. These standards are the reflection of the international consensus of specialists in this field. The Technical Committee No. 176 (ISO/TC “Quality Management and Quality Assurance”) created within the ISO in 1979 was in charge of the elaboration of generic standards with international application regarding this issue.

The International Standardization Organization (ISO) is an international federation of national standardization associations which has the purpose of promoting standardization and related activities in order to facilitate the exchange of goods and services and contribute to international co-operation at the scientific, economic, technological and intellectual level.  
[www.iso.org](http://www.iso.org)

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The ISO 9000 standard revision is based on the following eight quality management systems established in the ISO 9000 and 9004 standards:

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationship

In 1994, the first revision of the standards was finalised (ISO 9000:1994) and then a second revision was conducted which was published in December 2000 (ISO 9000: 2000). In this revision it was important to ensure that the standards were applicable to all type and size of organizations. The intention was also to avoid the creation of quality management systems for specific sectors.

The ISO/TC 176 Committee also elaborates particular management programmes based on the ISO 9000:2000 for sectors that need them. Other initiatives were taken into account in the revision of the standard such as the bases for the National Quality Award or the Total Quality Management programmes.

### **The approach based on processes**

This is probably the most important feature of the ISO 9000 standard. Among the ISO 9004-2000 family of standards (Quality Management Standards. Directives for the improvement of performance) this approach is specified in the following way:

“This standard promotes the adoption of an approach based on processes to develop, implement and improve efficiency and efficacy of a quality management system, in order to provide satisfaction to all interested parts through the fulfilment of its requirements”.

In order to have an efficient and effective functioning, an organization has to identify and manage several interrelated activities. A given activity, which uses resources and manages them in order to facilitate the transformation of inputs into results, is considered a process. Frequently, results of a process constitute directly the inputs of the following process.

The application of a processes system in an organization, together with the identification and interactions and management of these processes, can be referred to as an “approach of processes.”

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An advantage of this approach of processes is that it provides control over the connection between individual processes within the system of processes, as well as over its combinations and interactions.

When it is used on a quality management system, this approach gives emphasis to the importance of:

- Understanding and fulfilment of requirements
- The need to consider processes in terms of their contributing values
- Obtaining of results based on performance and efficacy of processes
- Continual improvement of processes based on objective measurement

The following standards make up for the ISO 9000:2000:

ISO 9000:2000 (Quality management systems. Fundamentals and vocabulary). It substitutes the ISO 8402 standard (Vocabulary) and it is based in the 9000-1:1994 (Guidelines for system implantation). This standard is not used for certification.

ISO 9001:2000 (Quality management systems. Requirements). It is used to get system certification. It describes the quality management requirements to assess the organization's ability to meet customer satisfaction. This standard substitutes the ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994 standards.

ISO 9004:2000 (Quality management systems. Guidelines for performance improvements). It provides guidelines but it does not describe requirements, thereby, it is not used for certification. It provides guidelines for continual improvement of the organization and satisfaction of all parties. This standard substitutes the ISO 9004-1/2/3/4:1994.

ISO 19011 (Guidelines on quality and/or environmental management systems auditing). It substitutes ISO 10011 (Quality auditing) and ISO 14010/11/12 (Environmental auditing).