ISO-9000 Standard

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- Quality Assurance always been tried to set up A quality management systems that meet world-class standards which asscepted at International Market.

- Over the last few years, the **ISO-9000** has become the most popular quality standard in the Pharma industry, with practically all major companies rushing to get ISO-9000-certified. In fact, companies not ISO-certified would find it difficult to do business, given that certification is a basic requirement of would-be customers. The ISO-9000 series of standards was developed by the International Organization for Standardization.

- ISO-9000 currently has three quality standards:

- **the ISO-9000:2000,**

- **the ISO-9001:2000,**

- **and the ISO-9004:2000.**

- Of these, only the ISO-9001:2000 outlines specific requirements for compliance, while the ISO-9000:2000 and the ISO-9004:2000 merely present information or guidelines.

- All of these quality standards are process-oriented, and not product-oriented(chamk,lightly). This means that ISO-9000 is more particular about how a company conducts its processes, and not what products it ships or level of product quality it has.

- The main objective of ISO is to facilitate international trade by providing a single internationally-accepted set of standards for everybody's reference.

- **Table 1. ISO9000-2000's Standards and Guidelines**

• **Standards and Guidelines**	• **Purpose**
• **ISO 9000:2000** • Quality Management Systems - Fundamentals and Vocabulary	• - Establishes a starting point for understanding the standards - Defines the fundamental terms and definitions used in the ISO 9000 family to avoid confusion in their use
• **ISO 9001:2000** • Quality Management	• - Defines the requirements for

Systems - Requirements	assessing the ability to meet customer and applicable regulatory requirements and thereby address(identi) customer satisfaction - Now the only standard in the ISO 9000 family against which third-party certification can be carried out
• **ISO 9004:2000** • Quality Management Systems - Guidelines for performance improvements	▪ - Provides guidance for continual improvement of the quality management system to benefit all parties through sustained customer satisfaction

- The first ISO standards were published in 1987, which were revised in 1994 as the ISO-9000:1994. The next and latest revision of ISO standards was released in 2000, and is therefore referred to as "ISO-9000:2000 Standards". The ISO-9000:2000, being process-oriented, can be applied to virtually any industry worldwide, and is certainly widely embraced in the semiconductor industry.

- The ISO-9000:1994 had 3 standards: the ISO-9001:1994, the ISO-9002:1994, and the ISO-9003:1994. ISO-9002:1994 and ISO-9003-1994 had been dropped, so companies who are certified to any of these two standards only should be re-certified to the ISO-9001:2000. Companies certified to the ISO-9001:1994 need to update their quality systems to the ISO-9001:2000 requirements for future recertification.

- Getting ISO-certified will not only bring about customer orders, it will also bring about efficiency and cost-effectiveness as a result of better process controls, operational systems, and problem resolution mechanisms.

- The process of getting ISO 9000-certified generally consists of the following steps: 1) development of a quality management system that meets the ISO 9000 standards; 2) conduct of internal audits to ensure that the quality system is working as planned; 3) invitation of an accredited external auditing body to audit the quality system and its implementation; 4) receipt of accreditation if the external auditor approved of the system; and 5) conduct of regular surveillance audits to maintain the certification.

- FOUNDED in 1946, ISO (International Organisation for Standardisation) consists of approximately 90 member countries at present and this number is expected to grow. With the exception of the electrical and electronic engineering industries (which are covered by International Electrotechnical Commission - IEC), the ISO is responsible for the promotion and development of international standards and related activities, including conformity assessments such as testing, inspection, laboratory accreditation, certification and quality assessments.

- **"The ISO 9000 series standards have been adopted by some 45 countries and its equivalent standard in the Indian context is the Bureau of Indian Standards' (BIS) 14000 series. In the United States, the series is known as the ANSI/ASQC Q 9000 series"**.
- The standard finds its origin in the European Community (EC) July 1985 product liability directives (also known as the single market directives) which state that for certain regulated products, manufacturers exporting to the EC and, eventually, to the European Free Trade Association, would need to have a well documented and implemented Quality Assurance System.
- The ISO 9000 series standards provide the requirements to which organisations desirous of certification must conform. One very important aspect of the standards is that they were very generic in nature and ingenuity is required while interpreting the standards' applicability to the industry or firm in question.

WHAT ARE THE ISO STANDARDS?

- Developed by the ISO Technical Committee 176, published in 1987 and updated approximately every five years, the standards comprise five documents whose focus is Quality Assurance Systems.
- These five documents are:

- **ISO 9000 -**
  Quality Management and Quality Assurance Standards - Guidelines for selection and use and avoid confusion in their use

- **ISO 9001 - Quality systems**

Model for quality assurance in design, production, installation and servicing. This is the most comprehensive(high) standard with 20 clauses.

- **ISO 9002 - Quality systems –**

Model for quality assurance in **production and installation**. This standard has 18 clauses(sarte).

- **ISO 9003 - Quality systems –**

Model for quality assurance in **final inspection and test**. Requires conformity with 12 clauses(sarte).

- **ISO 9004:2000**

- Provides guidance for **continual improvement of the quality management system** to benefit all parties through sustained customer satisfaction.

- Quality management and quality system elements - Guidelines.

- **ISO 9000 in India**

- While certain bodies like BVQI and DNV have already started operations in India, others are expected to be following suit. This is because the number of companies desirous of getting an ISO9000 series registration is ever increasing. In addition to the registrars, the number of people providing ISO related services such as consultancy on ISO implementation and lead assessor courses is also showing exponential growth. Apex industry associations such as the CII (Confederation of Indian Industry) have also started providing services such as the lead assessor course.

- **THE PROCESS**
- One of the important aspects of the ISO registration process is to verify whether the unit seeking registration is indeed doing what is being claimed in its quality manual.
- The best strategy to adopt when embarking on the road to ISO registration is to adopt a simple model: design a quality assurance model from bottom up to ensure that what is done is indeed what is documented. Most auditors, while doing third party audits for registration, like to follow the "show me mapping" process.
- The process should begin with a familiarisation with the standard, followed by an assessment of the current quality assurance system with a special focus on how it addresses the ISO requirements. Thereafter, corrective actions to remove the gaps should be initiated and continuous monitoring via internal quality audits should take place to prevent the degradation of the systems' entropy to a higher level. It is advisable to have the assistance of a consultant to guide the implementation efforts.
- The registrars, after conducting the audit, send their recommendations to the accrediting body, which gives the certification. After certification, periodic "unannounced" audits are conducted to ensure that the unit is complying with the requirements of the standard.
- Incidentally, it makes good sense to decentralise registration efforts both from the point of view of acquiring as well as retaining certification.
- The designed Quality Assurance system should:
  - suit the unit's need,
    not be restrictive to the point of being impractical
    be continuously upgraded.
- Indeed the implicit driving force behind the registration process should be the formulation of a well throughout, effective system designed to bring about improved performance.

- **THE BENEFITS OF REGISTRATION:**
- The ISO certification should note be seen as a panacea to all quality-related problems. In fact, it is only a base line model for quality assurance, which can and should be upgraded continuously. It represents a documented system for quality assurance and the real benefit (besides improved quality) it offers is that it raises the confidence of the third party dealing with the registered unit. There is indeed a facelift in the organisation's corporate image and not surprisingly, an advertising campaign follows the registration.
- There are other technical benefits of registration as well. Since the adoption of the Resolution of May 7, 1985, concerning a new approach towards technical

harmonisation and standardisation, the EC has adopted 8 modules, which apply to products covered under different directives of the Council. Companies exporting any of the products covered under the directives will need to conform to the requirements of the applicable module. Th eight modules are:

- Manufacturer's self declaration of conformity
  EC type examination
  EC declaration of conformity to type
  Production quality assurance (ISO 9002)
  Final inspection and testing (ISO 9003)
  Product verification by EC third party series production
  Same as F but for unit verification

- **Full quality assurance (ISO 9001)**
- Thus, if a company is exporting to the European Union, a product covered under one of the directives, which require conformity with modules D, E or H, the need for registration is done.
- Though ISO 9000, in its present form, does not deliver a comprehensive Total Quality Management System, it is rapidly gaining ground as the base line model. Its popularity is one the rise and even the Ministry of Small Scale Industries has declared an assistance of up to Rs 75,000 to the small scale unit which secures an ISO 9000 series registration which goes towards the cost of registration.
- What is true is that these international standards affect national standards, international trade and even national laws and regulations. The vigilance of the TC/176 committee (the international committee in charge of updating the ISO 9000 series) would probably ensure that standards are adopted. Therefore, companies wishing to increase or even maintain their niches in the European or global markets must seriously consider obtaining ISO registration as soon as possible.