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## ELEMENTS OF ISO

**Anita Sathe**

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**Abstract:-**The ISO 9000 series identifies the basic disciplines of a quality management system that can be used by manufacturers, suppliers, distributors and end users. The series specifies the national, regional and international accepted procedures and criteria that are required to ensure that product and services meet the customer's requirements. The present paper highlights on elements of ISO 9001.9002 1nd 9003.

**Keywords:**Elements of ISO 9001, 9002 and 9003.

### INTRODUCTION:

The ISO 9000 series identifies the basic disciplines of a quality management system that can be used by manufacturers, suppliers, distributors and end users. The series specifies the national, regional and international accepted procedures and criteria that are required to ensure that product and services meet the customer's requirements. These disciplines, procedures and criteria can be applied to any firm. The customers can also use it as a basis for assessing manufacturers, quality management system and to see that a supplier or service industry has the ability to provide satisfactory goods or services.

### Brief About ISO-9001, 9002 and 9003

The standard has been based on eight quality management principles. They are the basis for the revised standards, which are better aligned with the philosophy and objectives of most quality award programs. These principles are:

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

### ISO 9000 family standards are :

- Generic – i.e. they apply to any product or any organisation
- Non-prescriptive – i.e. they describe what management system functions shall or should be in place; but they do not prescribe how to carry out those functions.

They are founded on concept that assurance of consistent product quality is best achieved by simultaneous application of two kinds of standards

1. Product Standards (technical specifications) – which provide technical specifications that apply to characteristics of the

product

2. Quality System (management system) standards –provide the specifications for management system.

These standards are separate and complimentary. The management system is the domain of ISO 9000.

**•ISO9001**

ISO 9001 (model for quality assurance in design, development, production installation and servicing) provides details of the quality management system requirements used when a contract between two parties requires the demonstration of a manufacturer's ability to design and supply a quality product.

These requirements are aimed primarily at preventing non-conformity at all stages from design through to servicing and where the purchaser's requirements are provided in terms of performance-for example, when the customer specifies exactly what he requires in terms of how it should perform.

The standard applies to certain contractual situations and especially when confidence in product conformance can only be obtained through adequate demonstration of a manufacturer's capabilities (in terms of design, development, production, installation, testing and servicing). It is also applicable when a contract requires design efforts and the product requirements are stated principally in performance terms or their need to be established.

The manufacturer is thus required to provide assurance that they will conform to a specified set of standards (that have been provided by approved supplier) during several stages of a contract including design, development, production, Installation and after sales. ISO 9001 standard, therefore, provides detailed requirements of precisely what the manufacturer's quality management system should cover and to what degree. The standard emphasizes on documentation for quality management system.

**•ISO 9002**

ISO 9002 (model for quality assurance in production and installation) covers quality management system requirements where a contract between two parties requires the demonstration of a supplier's capability to control the processes that determine the acceptability of product supplied. These requirements are aimed primarily at detecting and preventing any non-conformity during production and installation and implementing the means to prevent their recurrence.

The standard also applies to certain contractual situations and especially when a contract between two parties requires the supplier to demonstrate that he is capable of providing an assurance of quality and product acceptability (during production and installation stages), that he is capable of preventing and detecting nonconformance during production and installation and that he is qualified to prevent its recurrence.

The specified requirements for products are normally stated in terms of an established specification or design and the demonstration of capability is normally achieved by providing a 'capability certification' that has originated from a third party evaluation process.

ISO 9002 is same as ISO 9001 except that the sections on design and servicing have been omitted. In addition slight manuscript amendments have been included in ISO 9002, to reflect the different emphasis on the requirement for quality.

**•ISO 9003**

ISO 9003 (model for quality assurance in final inspection and test) covers quality management system requirements for use when a contract between two parties requires demonstration of a supplier's capability (in final inspection and testing) and where the specified requirement for a product are stated in terms of an established specification or design. ISO 9003 also covers quality management system requirements, such as management responsibility over quality policy and organization and includes a useful section on definitions.

The standard is particularly useful when a contract between two parties requires the supplier to demonstrate that he has the capability of detecting and controlling product non-conformity during final inspection and test. It is also applicable to contractual situations where it is left up to the supplier to ensure that he is capable of maintaining the product throughout manufacture or supply and where he is requested to guarantee that the final product will be capable of not only meeting all of the specifications required but that it satisfies all the requirements of a quality article. ISO 9003 is very similar to ISO 9001 except some sections like design control, process control and servicing have been omitted and a slight manuscript amendments have been included to reflect the different responsibilities for assurance of quality.

**Table-**

Elements of ISO 9001,	9002	9003
Scope	<input type="checkbox"/>	<input type="checkbox"/>
Normative reference	<input type="checkbox"/>	<input type="checkbox"/>
Definitions	<input type="checkbox"/>	<input type="checkbox"/>
Quality system requirements elements	<input type="checkbox"/>	<input type="checkbox"/>
Management responsibility	<input type="checkbox"/>	<input type="checkbox"/>
Quality system	<input type="checkbox"/>	<input type="checkbox"/>
Contract review	<input type="checkbox"/>	<input type="checkbox"/>
Design control	<input type="checkbox"/>	N.A.
Document and data control	<input type="checkbox"/>	<input type="checkbox"/>
Purchasing	<input type="checkbox"/>	N.A.
Control of customer supplied product	<input type="checkbox"/>	<input type="checkbox"/>
Product identification and traceability	<input type="checkbox"/>	<input type="checkbox"/>
Process control	<input type="checkbox"/>	N.A.
Inspection and testing	<input type="checkbox"/>	<input type="checkbox"/>
Control of inspection, measuring and test equipments	<input type="checkbox"/>	<input type="checkbox"/>
Inspection and test status	<input type="checkbox"/>	<input type="checkbox"/>
Control of nonconforming product	<input type="checkbox"/>	<input type="checkbox"/>

Thus the elements of the ISO quality standards are highlighted. An organization tries to meet customer requirements by implementing the standards. ISO 9001 comprises of 20 quality system elements covering the areas of design, development, production, installation and servicing. This is most comprehensive and generally applies to manufacturing that design, develop, produce and install and service their own products. ISO 9002 requires adopting 19 elements out of 20 ISO 9001 quality system requirements excluding the design control element. It is applicable to facilities which produce, install and service their product, leaving design to customers or subcontractors. ISO 9003 is most limited in scope. It only incorporates 16 elements. This model only requires conformance to final inspection and test procedures and is most often used by testing laboratories and equipment distributors.

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