Quality Management and the ISO 9000

K. RAVINDRAN

The philosophy of modern methods of control and reliability spawned from a memo dated 16-05-94 from Walter A. Shewhart who proposed a control chart for the inspection data. This triggered an expansion of the concept of inspection from emphasis on detection and correction of sub-standard material to control of quality through analysis and prevention of quality problems. The modern approach to quality and reliability which embraces statistical applications, quality reliability and engineering, management, motivation etc. is primarily concerned with excellence in the design of the product, making of the product, use of the product and excellence throughout its life time.

Food processing and packaging companies can start on the journey towards world class quality by building a foundation using the quality tools: ISO 9000, Hazard Analysis Critical Control Points (HACCP) and Good Manufacturing Practices (GMP).

International Organization for Standardization

Initially conceived to foster development of uniform international manufacturing, trade and communication standards, the International Organization for Standardization (ISO) was established in 1946 with headquarters in Geneva, Switzerland. The purpose of ISO, is to promote the development of standardisation and related world activities in order to facilitate the international exchange of goods and services and to develop cooperation in intellectual, scientific, technological and economic activities. The genesis of the abbreviation of the organisation, ISO is related to isos, a Greek word meaning equal which is the root of the prefix iso In words such as isometric (of equal measure) or isonomy (equality of laws or of people before the law). The ISO with 14 founding members from Europe, the US, and the British Commonwealth has grown to a world wide

federation with over 100 member countries, with a decentralised pattern of work entrusted to over 180 active technical committees (TC) and over 620 active sub-committees, enlisting over 30,000 specialists engaged in developing international standards. ISO / TC-176 was established in 1979 to focus on standards in Quality Management and Quality Assurance which completed its task of development of the ISO core series of standards in 1987. These are a set of generic standards for global quality assurance for industry, business, education and government and can be applied to almost any situation where a quality system is needed. Unlike product standards these standards are for quality management systems.

ISO 9000 series of standards were modelled after the British Standard (BS) 5750. Standards Organizations in most countries have adopted these standards. The European Community has adopted the ISO Standards as the European Norm (EN) 29000 series. In the case of United States, these standards were assembled by the American National Standards Institute (ANSI) and the American Society for Quality Control (ASQC) into the ANSI/ASQC Q 9000 series. Bureau of Indian Standards (BIS) has adopted the ISO 9000 series of standards as the Indian Standards (IS) 14000 series.

1. The ISO 9000 standards are a series of five documents as shown in Table 1.

Table 1: *The ISO 9000 Series of Standards*

ISO standards	*Title*
ISO 9000	Quality management and quality assurance standards - Guidelines for selection and use.
ISO 9000-1	Guidelines for selection and use
ISO 9000-2	Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003
ISO 9000-3	Guidelines for the application of ISO 9001 to the development, supply and maintenance of software
ISO 9000-4	Guide to dependability programme management

ISO 9001	Quality systems - Model for quality assurance in design/development, production, installation and servicing
ISO 9002	Quality systems - Model for quality assurance in production and installation
ISO 9003	Quality systems - Model for quality assurance in final inspection and test
ISO 9004	Quality management and quality system elements - Guidelines
ISO 9004-1	Guidelines
ISO 9004-2	Guidelines for services
ISO 9004-3	Guidelines for processed materials
ISO 9004-4	Guidelines for quality improvement
ISO 9004-5	Guidelines for quality plans
ISO 9004-6	Guidelines for project management
ISO 9004-7	Guidelines for configuration management

The standards are of two types.

(a) Conformance

ISO: 9001	It includes all elements in the promotion cycle from designing to servicing, and contains 20 requirements - Design products
ISO 9002	Same as ISO 9001, except that there are no requirements for design control. (Manufacture only)
ISO 9003	For final inspection and test. (Neither design nor manufacture)

(b) Guidance

ISO 9000	It is a guidance standard for selecting the proper conformance standard
ISO 9004	It gives details regarding quality management and quality system elements.

Table 2. *List of Quality System Requirements*

Quality System Requirements	ISO 9001	9002	9003
1. Management Responsibility	x	x	x
2. Quality System	x	x	x
3. Contract Review	x	x	x
4. Design Control	x		
5. Document and data control	x	x	x
6. Purchasing	x	x	
7. Control of Customer-Supplied Product	x	x	x
8. Product Identification and Traceability	x	x	x
9. Process Control	x	x	
10. Inspection and Testing	x	x	x
11. Control of Inspection, Measuring and Test Equipment	x	x	x
12. Inspection and Test Status	x	x	x
13. Control of Non-Conforming Product	x	x	x
14. Corrective and Preventive Action	x	x	x
15. Handling, Storage, Packaging, Preservation and Delivery	x	x	x
16. Control of Quality Records	x	x	x
17. Internal Quality Audits	x	x	x
18. Training	x	x	x
19. Servicing	x	x	
20. Statistical Techniques	x	x	x

ISO 9001, ISO 9002 and ISO 9003 are models for quality assurance in an organisation, while ISO 9004 provides detailed elements to consider when designing or revising a quality management system. Companies can register their quality management systems to only ISO 9001, 9002 and 9003. ISO 9000 is both the short cut name for the overall series of five documents and the specific name for the first one in the series. ISO 9000 provides guidance on which of the three models to choose. ISO 9001 is the most

comprehensive standard. It requires a company to develop a system that meets all 20 elements of the standard. For a company undertaking product development and manufacture, ISO 9001 is suitable. ISO 9002 permits registration of a quality system when design control is not required by contractual requirements. For a control manufacturer carrying out no R & D, ISO 9002 permits registration of a quality system when design control is not required by contractual requirements. For a contract manufacturer carrying out no R&D ISO 9002 can be selected. ISO 9003 is the least comprehensive quality system standard. It requires a quality system that is composed of only 16 elements. It is intended to serve as a model when specified requirements are to be assured solely at final inspection and test. For a commodity supplier ISO 9003 is suitable. Table 2 shows the requirement headings included in models ISO 9001, ISO 9002 and ISO 9003. ISO 9000 standards require a documented quality system.

The quality policy is the shortest document in the system; one page or less is sufficient. Quality policy defines the company's quality objective and its commitment to it and links this to customers' needs and the wider goals of the business. Quality policy is often displayed around the premises, since the staff are expected to know it. It is normally included in the quality manual. The quality manual is a small 25 to 30 page document. Its purpose is to state how the requirements of ISO 9000 are met in the company's own quality system. Quality procedures are at the heart of the quality system. They provide further details on how the information in the quality manual is deployed and implemented. Work instructions describe in detail how the procedures are accomplished. ISO 9000 standards require quality records to be kept. The record keeping system should provide sufficient documentation to ensure that a task is being done correctly. Then an auditor can verify whether the procedures and work instructions are being done according to plan.

A company will follow the steps given below for obtaining registration to an ISO standard.

1. Commitment by top management
2. Formation of ISO steering group

3. Training in ISO
4. Development of a quality manual
5. Start-up of internal audits. The audits determine the effectiveness of the quality management system. The company must also develop a corrective action system to identify and eliminate root cause of the problems.
6. Selection of a registrar
7. Pre-assessment. Pre-assessment of the quality system can be carried out by a registrar or a consultant. Pre-assessment reveals major problems in the quality system.
8. Improvement of system. Deficiencies revealed during the pre-assessment are corrected and improved quality systems are implemented.
9. Assessment. Assessment is carried out by a registrar.

The registrar or audit team will first determine whether the quality manual conforms to the appropriate ISO standard. Then the team will determine whether the procedures and work instructions conform to the quality manual. Finally the team will determine whether employees are conducting their jobs in accordance with the procedures and work instructions.

Non-conformities raised by the audit team are of two types; minor and major. Minor non-conformities are expected to be solved within a reasonable time using the corrective action procedure of the company. Hence ISO 9000 is awarded. But in the case of major non-conformities, the company has to make and implement the improvements in the quality system. Then re-auditing is conducted and ISO 9000 is awarded.

10. Surveillance. Once the initial registration is achieved, internal audits and third-party surveillance audits must be conducted to maintain registration. Usually third-party surveillance audits are conducted for continued compliance in every six months.

After obtaining registration to an ISO standard, companies can go further from just meeting customers' requirements. The concept of

delighting customers leads into Total Quality Management (TQM) which is often considered a step beyond quality assurance.

The ISO 9000 standards nomenclature for different countries, including India, is given in Table 3.

Table 3. *World-wide Equivalents of ISO 9000 Standards*

Country	ISO 9000 Standard Nomenclature
Australia	AS 3900
Belgium	NBN-EN 29000
Brazil	NB 9000
Canada	Z 299
Chile	NCH-ISO 9000
China	GB/T 10300
Denmark	DS/ISO 9000
Finland	SFS-ISO 9000
France	NF EN 29000
Germany	DIN ISO 9000
Greece	ELOT EN 29000
Iceland	IST ISO 9000
India	**IS 14000**
Ireland	I.S./ISO 9000
Italy	UNI/EN 29000
Japan	JIS Z 9900
Mexico	NOM-CC 2
Netherlands	NEN ISO 9000
Norway	NS ISO 9000
Portugal	EM 29000
Singapore	SS 306
South Africa	SABS 0157
Spain	UNE 66-9000
Sweden	SS-ISO 9000
Switzerland	SN-EN 29000
United Kingdom	BS 5750
United States	Q 9000

Dr. Deming, who is credited with popularising quality control in Japan in the early 1950's emphasizing a cultural range from short-term profitability to long-term constancy of purpose for improvement of product and service, has enunciated the following universal 14 points aiming at a commitment to quality, which he defined as a predictable degree of uniformity and dependability at low cost and suited to the market.

1. Create constancy of purpose for the improvement of product and service.
2. Adopt a new philosphy. Teach it to employees, to customers, to suppliers. Put it into practice, in other words - the new philosophy - which is one of cooperation, win-win, everybody wins.
3. Cease dependence on inspection to achieve quality. Much better to improve the process in the first place so that we don't produce so many defective items - or none at all. Build quality into the product in the first place.
4. End the practice of awarding business on the basis of price tag alone. Instead, minimize total cost in the long run. That means one has to predict the cost of use of any product or service.
5. Improve constantly the system of production and service to improve quality and productivity and thus constantly decrease costs.
6. Institute training for skills. People learn in different ways, and training must take account of those differences.
7. Adopt and institute principles for the management of people. I am referring to the management of people for recognition of different abilities, capabilities, aspirations, Institute leadership.
8. Drive out fear, build trust so that everyone will work effectively for the company. Its purely a matter of management.
9. Break down barriers between departments. People in research, design, sales and production must work as a team to foresee problems of production as well as after-sale use.

10. Eliminate slogans, exhortations and targets asking for zero defects and new levels of productivity.

11. Eliminate management by numerical quotas. A numerical goal or quota accomplishes nothing. Substitute leadership.

12. Remove barriers that rob people of joy in their work. This will mean abolishing the annual rating or merit system which ranks people, creates competition and conflict.

13. Institute a vigorous program of education and self-improvement.

14. Accomplish the transformation; that is, continue to study the new philosophy. Develop a critical mass in your organization that will bring about the transformation. The transformation is everybody's job.

Juran, the founder of Juran Institute, Connecticut, USA has promoted the concept of Managing Business Process Quality which is a technique for executing cross functional quality improvement. Juran defines quality as fitness for use in terms of design, conformance, availability, safety and field use. This lays emphasis more on the point of view of the customer and relies on systems and problem-solving techniques.

Customers are increasingly prescribing stringent requirements and international competition is mounting. Quality has become a competing marketing strategy and there has been an increasing stress on total quality management (TQM) as a philosophy of management involving systems approach that takes into account every interaction between the various elements of the organisation. It considers quality in terms of all functions of the organisation and is a start to finish process that integrates interrelated functions at all levels. This results in higher overall effectiveness of the system than the sum of the individual outputs from the sub-systems.

Reengineering is a latest concept which is gaining popularity and which looks at the fundamental process of business from a cross-functional perspective to ensure customer satisfaction in order to create a market-driven manufacturing system. "By focussing on making improvements in all dimensions of the service organization - human dimension, work process

dimension and the technological dimensions - reengineering helps companies overcome systematic work barriers that interfere with efforts to achieve higher levels of customer satisfaction" (R. Janson). "Quality can be attained by creating a problem-solving mind set based on facts, a process oriented view based on prevention instead of inspection, an environment of continuous improvement driven by employee involvement and an overriding priority of satisfying customer needs." (H.G. Menon). Organisations that deliver quality and meet customer satisfaction alone will prosper and sustain in the 3rd millennium as quality begins and ends with the customer.