ISO 9001:2008 DIAGNOSTIC TOOL

IMPLEMENTING QUALITY MANAGEMENT SYSTEMS

International
Trade
Centre

ISO 9001:2008 DIAGNOSTIC TOOL

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Abstract for trade information services

Checklist of questions covering various aspects of setting-up, implementation and certification of a quality management system according to ISO 9001:2008, aimed at small and medium enterprises − helps to determine the status of an enterprise's quality system vis-à-vis the requirements of the ISO 9001 Standard; allows to identify areas for improvement for implementing an ISO 9001quality management system, or certification to the Standard; includes a bibliography of information sources relevant to the implementation of ISO 9001:2008. (Updates the ITC tool "ISO 9001 Fitness Checker", published in 2002).

Descriptors: **Quality Management, Quality Systems, Standards, Certification**.

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English

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Foreword

Quality is a prerequisite for successful market access and for improving the competitiveness of exporters. As a small and medium-sized enterprise, you are aware of the importance of quality systems to ensure effective and efficient functioning of your enterprise. If you have asked yourself what exactly is involved and how ready your company is to implement an ISO 9001 Quality Management System, then this *ISO 9001:2008 Diagnostic Tool* will provide you with the answers.

The ISO 9001:2008 Diagnostic Tool helps you to determine the status of your enterprise's quality system vis-à-vis the requirements of the ISO 9001 Standard, and therefore helps you to identify the main areas for improvement on your path to implementing an ISO 9001 quality management system, or certification to ISO 9001, if you wish. The Tool gives you an overview of the processes involved for your enterprise by taking you through the requirements of the standard in a step-by-step manner.

The Tool consists of a series of questions grouped under four parts, each covering a particular aspect of your enterprise's journey to implementing ISO 9001. They do not all have to be completed in one go. If you wish to split your assessment into consecutive parts, you can continue from where you left off in the previous part. Each question is linked to the relevant clause of the ISO 9001:2008 standard and to an explanation that may be of use to you.

For each question, it is possible to generate a quantifiable assessment of the compliance of your business to ISO 9001 requirements by assigning a score. An aggregation would give an assessment report with a general score for each part of the questionnaire. A final aggregation would give a general score to the entire questionnaire and a qualitative assessment of the maturity level of your company towards implementing ISO 9001.

The Tool has been developed for businesses in developing countries and economies in transition using the self-assessment questionnaires, whereby the questions and explanations are written in a simple and user-friendly language for SMEs.

The *ISO 9001:2008 Diagnostic Tool* is an update of the ITC publication ISO 9001 Fitness Checker, developed under the Programme for Competitiveness Improvement of SMEs (ProCIP) and published in 2002. This current version takes account of the latest edition of the standard published in 2008 and serves as a diagnostic tool for SMEs to improve their international competitiveness in their endeavour to export.

Acknowledgements

Contents

Abbreviations

The following abbreviations are used:

CAD   Computer-aided design
CB   Certification body
ITC   International Trade Centre
ISO   International Organisation for Standardization
QMS   Quality Management System
MR   Management representative
SMART   Specific, Measurable, Achievable, Realistic and Time bound (objectives)
SMEs   Small and medium-sized enterprises

Introduction

The *ISO 9001:2008 Diagnostic Tool* takes you through four parts on your journey to implementing ISO 9001:2008. These are the following along with the reference to ISO 9001:2008 clauses:

- Planning (5.2 to 5.5) and Resource Management (6.2 to 6.4)

- Key Business Processes (7.2 to 7.6)

- Measurement, Analysis and Improvement (8.1 to 8.5)

- Documentation (4.1 and 4.2) and Implementation of QMS (5.1 and 5.6)

The *Diagnostic Tool* enables you to score and assess your readiness to implement an effective ISO 9001:2008 Quality Management System.

At the end of the *Diagnostic Tool*, you will find a Bibliography that will enable you to obtain additional sources of information on your path to implement ISO 9001:2008.

The *ISO 9001:2008 Diagnostic Tool* should be used in conjunction with ISO 9001:2008, Quality management systems – Requirements.

QUESTIONNAIRE

Part 1 – Planning and Resource Management

No.	Question	ISO 9001 Clause	Explanation	Score *(see note below)*
Q.1.1	Does your organization's Top Management have a clear and strong "customer focus", i.e. do they know their customers' needs and expectations for the products that the customers buy from your organization?	5.2	E.1.1	
Q.1.2	Has your Top Management put in place a Quality Policy expressing their overall intentions and directions related to quality?	5.3	E.1.2	
Q.1.3	Do you have clearly defined and measurable quality objectives that support your Quality Policy?	5.4.1	E.1.3	
Q.1.4	Does your organization carry out the planning of the Quality Management System?	5.4.2	E.1.4	
Q.1.5	Does your organization have a clearly defined organizational structure with levels of authority assigned to various functions and people?	5.5.1	E.1.5	
Q.1.6	Has your organization's Top Management identified a "management representative" from its own management to coordinate the activities of developing and implementing the Quality Management System?	5.5.2	E.1.6	
Q.1.7	Are there effective communication processes in your organization to inform employees how well the organization is doing in achieving its objectives and other matters relating to quality?	5.5.3	E.1.7	
Q.1.8	Are your employees competent to perform their assigned tasks and duties?	6.2.1 and 6.2.2	E.1.8	
Q.1.9	Does your organization provide and maintain infrastructure such as building, utilities, equipment, software and supporting services needed to achieve product conformity?	6.3	E.1.9	
Q.1.10	Do your plant, office and other work areas contribute to ensuring conformity of product and service quality?	6.4	E.1.10	
			Total Score[1]	

Note: To Score use this table

0	You do not understand this or believe it is necessary.
1	You understand this activity is a good thing to do, but do not do it.
2	You do this but not systematically.
4	You are complying with this.
5	You are not only complying but also making improvements wherever possible.

To obtain the assessment report, go to the section "ASSESSMENT REPORT – PART 1".

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[1] Add the score of each question to calculate the total score.

Part 2 – Key Business Processes

No.	Question	ISO 9001 Clause	Explanation	Score *(see note below)*
A. Customer-Related Process				
Q.2.1	Does your organization have effective arrangements to communicate with customers regarding product information, enquiries/orders and customer feedback?	7.2.3	E.2.1	
Q.2.2	Does your organization always determine the exact details of the product/services needed by the customer including post-delivery requirements?	7.2.1	E.2.2	
Q.2.3	Does your organization review the product requirements given by customers and resolve the ambiguities, if any?	7.2.2	E.2.3	
B. Design and Development				
Q.2.4	Does your organization prepare a design and/or development plan for designing the product and/or service you sell?	7.3.1	E.2.4	
Q.2.5	Does your organization before preparing a design and/or developing a product, determine inputs relating to product requirements?	7.3.2	E.2.5	
Q.2.6	Does your organization ensure that the design and/or development output clearly defines characteristics of the product?	7.3.3	E.2.6	
Q.2.7	Does your organization review the design and/or development at suitable stages?	7.3.4	E.2.7	
Q.2.8	Does your organization carry out design and/or development verification to check if design output meets the design input requirements?	7.3.5	E.2.8	
Q.2.9	Does your organization carry out validation of design and/or development to check if the product/service will meet the intended purpose?	7.3.6	E.2.9	
Q.2.10	Does your design and/or development process provide for the control and approval of design changes and the management of these modifications?	7.3.7	E.2.10	
C. Purchasing				
Q.2.11	Have you evaluated your suppliers to decide if they are capable of meeting quality requirements for product and services which you intend to purchase from them?	7.4.1	E.2.11	
Q.2.12	Do you have a process to check the adequacy of information contained in purchase orders before you release the same to the suppliers?	7.4.2	E.2.12	
Q.2.13	Do you have a process to verify/inspect the products you receive from your suppliers?	7.4.3	E.2.13	
Q.2.14	Is your organization outsourcing some of its processes and do you exercise control over such outsourced processes?	4.1	E.2.14	

	D. Production and Service Provision			
Q.2.15	Does your organization carry out production and service delivery under controlled conditions?	7.5.1	E.2.15	
Q.2.16	Does your organization need to validate (qualify) such process (es) where the deficiency in the product of such process (es) only becomes known when the product is in use?	7.5.2	E.2.16	
Q.2.17	Does your organization need to identify its products, maintain their inspection/test status and keep traceability right through the incoming to delivery stages of the product?	7.5.3	E.2.17	
Q.2.18	Does your organization exercise due care on customer property either for use or for incorporation in your product?	7.5.4	E.2.18	
Q.2.19	Does your organization handle its products with care, both during internal processing and during delivery to customer?	7.5.5	E.2.19	
Q.2.20	If monitoring and/or measuring equipment are used by your organization, do you ensure that their accuracy is maintained?	7.6	E.2.20	
			Total Score[2]	

Note: To Score use this table

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1	You understand this activity is a good thing to do, but do not do it.
2	You do this but not systematically.
4	You are complying with this.
5	You are not only complying but also making improvements wherever possible.

Note:

If any of the above requirements is not applicable to your organization, then do not give a score against those questions and indicate NA (not applicable) in the score box. Total score obtained by you should be evaluated out of the remaining total score. For example if 2 requirements are not applicable then your score should be evaluated out of total 90 = (20-2) x 5 instead of maximum 100 = (20 x 5).

To obtain the assessment report, go to the section "ASSESSMENT REPORT – PART 2".

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[2] Add the score of each question to calculate the total score.

Part 3 – Measurement, Analysis and Improvement

No.	Question	ISO 9001 Clause	Explanation	Score *(see note below)*
Q.3.1	Does your organization plan for monitoring, measurement, analysis and improvement processes needed by your organization?	8.1	E.3.1	
Q.3.2	Does your organization have a process to monitor measure and analyse customer satisfaction?	8.2.1	E.3.2	
Q.3.3	Has your organization effectively implemented the procedure for internal QMS audits?	8.2.2	E.3.3	
Q.3.4	Does your organization monitor and/or measure QMS processes to check if the processes are achieving targeted results?	8.2.3	E.3.4	
Q.3.5	Does your organization carry out inspection and testing of product at various stages of production/service provision?	8.2.4	E.3.5	
Q.3.6	Does your organization effectively control the non-conforming product so that it is not unintentionally used by or delivered to the customer?	8.3	E.3.6	
Q.3.7	Does your organization analyse data generated as a result of monitoring and measurement of processes and products to demonstrate effectiveness of QMS?	8.4	E.3.7	
Q.3.8	Does your organization continually improve its QMS	8.5.1	E.3.8	
Q.3.9	Does your organization take effective corrective actions needed to eliminate the root cause of deviations/problems?	8.5.2	E.3.9	
Q.3.10	Does your organization take effective preventive actions to prevent potential problems that can result in unnecessary cost and dissatisfied customers?	8.5.3	E.3.10	
			Total Score[3]	

Note: To Score use this table

0	You do not understand this or believe it is necessary.
1	You understand this activity is a good thing to do, but do not do it.
2	You do this but not systematically.
4	You are complying with this.
5	You are not only complying but also making improvements wherever possible.

To obtain the assessment report, go to the section "ASSESSMENT REPORT – PART 3".

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[3] Add the score of each question to calculate the total score.

Part 4 – Documentation and Implementation of QMS

No.	Question	ISO 9001 Clause	Explanation	Score (see note below)
Q.4.1	Has your Top Management taken a considered decision for implementing ISO 9001 for organizational benefit?	0.1	E.4.1	
Q.4.2	Is your organization aware of the steps involved in the systematic development of a Quality Management System?	4.1	E.4.2	
Q.4.3	Is your Top Management committed to implementing and continually improving the effectiveness of the QMS?	5.1	E.4.3	
Q.4.4	Does your organization determine the processes, needed for the QMS and decide their interaction, including criteria for their effective operation and control?	4.1	E.4.4	
Q.4.5	Do you have a Quality Manual that describes the core elements of QMS and the interaction of various QMS processes?	4.2.2	E.4.5	
Q.4.6	Do you have documented procedures for control of documents; control of records; internal audit; control of nonconforming product; corrective action; and preventive action, that describe how these six processes and their related work activities are performed?	4.2.1(c)	E.4.6	
Q.4.7	Does your organization require documents and records other than the six mandatory documented procedures and 21 records as listed in the standard for ensuring effective, planning, operation and control of its processes?	4.2.1(d)	E.4.7	
Q.4.8	Are your organization's documents kept under proper control as specified in your procedure on the control of documents?	4.2.3	E.4.8	
Q.4. 9	Are all the necessary records created and controlled as described in your documented procedure on the control of records?	4.2.4	E.4.9	
Q.4.10	Is your QMS reviewed by top management regularly and in a planned manner for assessing its suitability, adequacy and effectiveness?	5.6	E.4.10	
			Total Score[4]	

Note: To Score use this table

0	You do not understand this or believe it is necessary.
1	You understand this activity is a good thing to do, but do not do it.
2	You do this but not systematically.
4	You are complying with this.
5	You are not only complying but also making improvements wherever possible.

To obtain the assessment report, go to the section "ASSESSMENT REPORT – PART 4".

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[4] Add the score of each question to calculate the total score.

EXPLANATION

Part 1 – Planning and Resource Management

Q.1.1 ***Does your organization's Top Management have a clear and strong "customer focus", i.e. do they know their customers' needs and expectations for the products that the customers buy from your organization?***

E. 1.1 Customers, all over the world and at all times, demand to be assured that the product or service for which they are paying will meet their needs and expectations (specifications) and that the product will perform as expected. If your customers are not satisfied, they can always buy from another supplier. In this sense, therefore, customer focus should be a core principle of your business. It is not optional. It is essential for survival.

Customer focus means producing and supplying the products and services that are liked and wanted by the customers. Customer satisfaction/dissatisfaction depends on a number of positive and negative factors, which are experienced by the customer. The more positive factors present, the higher the customer satisfaction. Following is the minimum you can do to achieve customer satisfaction.

- Determine the customer needs;

- Design a product which responds to customer needs;

- Produce and deliver the products as per the design;

- Provide effective after-sales service;

- Handle complaints quickly if received from the customer;

- Monitor the customer perception.

- Based upon the customer feedback and changing requirements of the market keep improving the quality of your products and services to delight the customer.

As the standard of living improves demand for better product and services also increases.

Your Top Management should therefore ensure a continuing and successful relationship with customers, potential customers and the end users of your product. This requires them to understand the customers' needs and expectations and to find ways to meet these needs.

It is also vital to be aware of the activities of your competitors in your market sector. You can be blindsided by changes in the market when a competitor introduces new product features or changes the price. It may also happen that new materials or technology may become available that change the market demand or there may be changes in the product related regulations which may undermine your position in the market. To be successful you should keep track of such changes and make modifications in the product features accordingly with a focus on improving customer satisfaction.

Q.1.2 ***Has your Top Management put in place a Quality Policy expressing their overall intentions and directions related to quality?***

E.1.2 The purpose of a Quality Policy is to keep reminding your employees as to what is expected of them in satisfying the customers. A statement in the quality policy towards commitment of continually improving effectiveness of the quality management system will also remind your employees to be ready to face changes in customer needs, market conditions, economic conditions, etc.

While framing the quality policy your Top Management should also ensure that it can be easily translated into objectives. For example a Quality Policy may read as follows:

'We are committed to providing products that are delivered on time and meet customer requirements. We achieve this through product and process improvement and cost reduction activities'.

From the above policy, *inter alia*, the following objectives can be derived.

Policy	Objective
We are committed to provide products that are delivered on time	95% on time delivery
Cost reduction activity	10% reduction of cost of poor quality as percentage of sales

Once the above objectives are met, it can be said that you are effectively meeting the commitments made in your company's quality policy.

A statement of the quality policy in a nice frame displayed at the reception area of your company may impress visitors, but unless it is understood and adhered to by the employees it will have no effect on satisfying the customers.

Q.1.3   *Do you have clearly defined and measurable quality objectives that support your Quality Policy?*

E.1.3   The requirement of ISO 9001:2008 on quality objectives states that the quality objectives:

- Should be consistent with your quality policy;

- Should be set for the conformance of both product and the Quality Management System;

- -Should be set up at relevant functions (departments) and levels (sections/persons) within your company;

- Should be convertible to very specific and measurable targets so that the employees can focus on them during their work activities to achieve them.

The quality objectives should preferably be SMART (Specific, Measurable, Achievable, Realistic and Time bound). For example:

- Percentage of times meeting agreed customer requirements within a certain period of time, e.g. to achieve 95% on time delivery of product to the customer within a period of three months;

- Identifying a target number of improvement opportunities (for example each employee to give at least one suggestion every six months leading to improvement in QMS);

- Minimizing the cost of rework or scrap, e.g. 10% reduction in internal failures per 1000 units of production every year, etc.

In some organizations objectives are referred to as "key success factors". You should identify your own key success factors depending on the past performance and resource availability. When setting up quality objectives, look for the indicators that your employees can relate to their work area and that can be measured such as:

- Reducing the time it takes to produce each item;

- Reducing defects during production;

- Achieving cost reduction;

- Improving productivity;

- Increasing market share, etc.

Your employees must know and understand the specific quality objectives that have been set for their function /level and how they can achieve them. It is also important to tell them regularly how well these objectives are being met and where improvements are required.

Objectives must be reviewed and revised from time to time as part of the continual improvement process.

Q.1.4   *Does your organization carry out the planning of the Quality Management System?*

E.1.4   QMS planning includes:

- Determining sequence and interaction of processes;

- Determining criteria and methods to ensure effective operation and control of processes;

- Carrying out monitoring and measurement of processes;

- Taking corrective actions and/or improvement actions on the results of monitoring and measurement of processes.

For effective planning and control of QMS processes it is advisable to document the outputs of QMS planning so that all your concerned employees will follow the system as defined.

Furthermore, for each quality objective, you should set up a clear plan defining how and by whom the objective is to be achieved, a time frame for achieving the objective, the person responsible for the same and the resources needed.
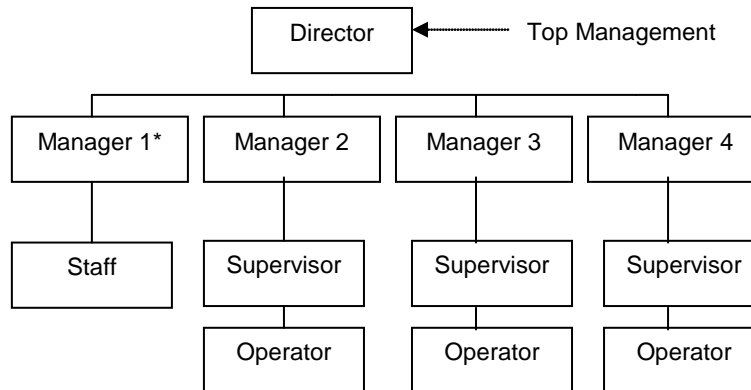
You should also ensure that the integrity of your QMS is maintained when changes like personnel changes, adding new product lines, major plant maintenance, mergers, acquisitions, etc take place in your organization.

Q.1.5   *Does your organization have a clearly defined organizational structure with levels of authority assigned to various functions and people?*

E.1.5 You should ensure that the specific responsibilities and authorities within the Quality Management System are formally defined and communicated to all your concerned employees.

Organizations normally use an organization chart to show the reporting lines of various functions and levels. A typical example is shown in figure1.

Figure 1 – A typical organization chart

* Also acts as management representative

What an employee is expected to do is his/her responsibility while what he/she is allowed to do is the authority of the employee. For example, monitoring the process parameters at defined intervals is the responsibility of the employee and, if he/she is allowed to either do adjustments in the process or stop the process in the event of deviations, this will be his/her authority. Within QMS you should specifically define responsibilities and authorities for the following activities/processes.

- Authority for approval of various documents like quality manual, procedures, quality plans, work instructions etc.(Clause 4.2.3 a) (refer E.4.8).

- Responsibility and authority of management representative (Clause 5.5.2) (refer E.1.6).

- Responsibility and authority for review of product requirements given in customer order (Clause 7.2.2) (refer E.2.3).

- Responsibility and authority for review of design inputs, review of design, verification of design, validation of design, approval of design changes, etc. (Clauses 7.3.1 to 7.3.7) (refer E.2.6 to E.2.10).

- Responsibility and authority for examining adequacy of purchase information being sent to supplier (Clause 7.4.2) (refer E.2.12).

- Responsibility and authority for managing the internal audit process including verification of effectiveness of the corrective action taken on audit nonconformities (Clause 8.2.2) (refer E.3.3).

- Authority for approving deviations, if any, in the plan for monitoring and measurement of product (Clause 8.2.4) (refer E.3.5).

- Authority for release of product for delivery to customer (Clause 8.2.4) (refer E.3.5).

- Responsibility and authority for dealing with nonconforming product including approval of release of product with concessions (Clause 8.3) (refer E.3.6).

- Responsibility and authority for taking corrective actions on product/process nonconformities including customer complaints (Clause 8.5.2) (refer E.3.9).

- Responsibility and authority for initiating and taking preventive actions (Clause 8.5.3) (refer E.3.10).

In addition to the above, responsibilities and authorities for managing other processes of QMS should also be defined. Specific responsibilities and authorities of Top Management include defining Quality Policy (Clause 5.1 b), ensuring that quality objectives are established (Clause 5.1 c), appointing the management representative (Clause 5.5.2), conducting management review (Clause 5.1 d) and providing resources (Clause 5.1 e).

Q.1.6 *Has your organization's Top Management identified a "management representative" from its own management to coordinate the activities of developing and implementing the Quality Management System?*

E.1.6 ISO 9001:2008 in clause 5.5.2 states that a person from the organization's own management should be assigned the responsibility and authority for ensuring that the processes needed for the Quality Management System are established, implemented and maintained. The term "own management" here implies that such person should not be an outsider (such as a consultant working on a part-time basis).The Standard identifies this person as the "management representative" (MR) who is appointed by the Top Management of the organization.

The job of MR is usually given to a person in addition to his/her other tasks and duties. You may assign this task to a person either from the quality department or other departments. In small organizations, the owner/partner/director of the company may also act as the management representative. MR is also responsible for promoting awareness of customer requirements throughout the organization, e.g. through training, internal communications, setting processes for maintaining timely communication with customers including settlement of customer complaints, etc. One more responsibility which your MR will need to undertake is reporting to the Top Management about possible improvements which can be made in your QMS. MR generally also does liaison with external parties on all matters relating to QMS, e.g. external trainers, consultants, standards bodies, testing/calibration laboratories, certification bodies, etc.

While appointing MR you may like to inform your other employees that he/she is only a coordinator/facilitator for QMS while the responsibility for managing various processes of QMS lies with all those who have been assigned responsibilities for the same.

Q.1.7 *Are there effective communication processes in your organization to inform employees how well the organization is doing in achieving its objectives and other matters relating to quality?*

E.1.7 You should set up effective communication processes This will enable you to:

- Transmit and receive information quickly;

- Build trust among everyone in the organization;

- Inform employees whenever changes are made to the quality policy, the quality objectives and the quality management system;

- Find ways to improve your processes.

The ways in which the communication takes place will depend on the size and culture of the organization. Some examples of communication channels are newsletters, notice boards, intranet, meetings, training and other such media. In smaller companies the communication moves faster from owners/directors to employees and vice-versa.

Q.1.8   *Are your employees competent to perform their assigned tasks and duties?*

E.1.8   Competence is the combination of the appropriate education and training with the required experience and skill for a specific job. You need to review the experiences, qualifications and skills of your managers and employees relative to the competence needs for the operation and control of your processes. If there are gaps in the competence levels it will be necessary for you to provide retraining or take other suitable actions such as attachment with other competent employee, etc. After providing such training you should examine if it has served the purpose. Internal auditors also need training in the tools and techniques of auditing.

Small organizations have a limited number of employees and they frequently need to share their duties and responsibilities when there is illness, holidays and emergencies. Every employee must be aware of the following:

- What is expected of him/her (responsibility)?

- What is he/she allowed to do (authority)?

- What is the relevance and importance of their activities?

- How do their responsibilities relate to those of other employees in the organization?

- How do they contribute to achieving the quality objectives relevant to their function?

It is important to keep records of education, experience, skills and training of your employees.

Q.1.9   *Does your organization provide and maintain infrastructure such as building, utilities, equipment, software and supporting services needed to achieve product conformity?*

E.1.9   Providing adequate workspace, suitable equipment, reliable utilities (power supply, water supply, steam/compressed air supplies, etc), support services (transport for safe handling and delivery of raw material/finished product, communication services like phone/fax, information system, etc) are a pre-requisite for producing conforming product/services. You should plan and regularly review the adequacy of such infrastructure and allocate resources for timely provision of the same.

Furthermore, unless you regularly maintain the infrastructure, the desired result (conforming product) will not be achieved. In a manufacturing environment the processing plant, machinery and any other equipment on which process capability depends need to be maintained. Similarly, in a service environment if there is any equipment on which capability of your service process depends (e.g. electronic printer in a bank to print customer account details asked by customer across the front desk), the same should also be maintained.

Q.1.10   *Do your plant, office and other work areas contribute to ensuring conformity of product and service quality?*

E.1.10   The work environment is defined in the international standard, ISO 9000:2005, as a set of conditions under which people operate and includes physical, social and psychological environmental factors. Therefore your plant, office and work area should be appropriate for the product and for the people producing the product because it affects both. Physical factors of the work environment may include hygienic and safe work place, temperature, light, humidity, cleanliness, vibrations, pollution, air flow, etc.

You should control the physical factors firstly within the levels required by the law, secondly within the level necessary to prevent deterioration of product, thirdly as necessary for people to perform their job efficiently (e.g. sound limits of a machine/equipment are prescribed in legislations, such machines/equipment should have acoustic control or employees working near such machines/equipment should be provided with ear plugs/mufflers). This will also help in achieving a higher level of productivity. It has been proven that highly productive employees usually also produce high quality products.

Part 2 − Key Business Processes

A. Customer-Related Process

Q.2.1   ***Does your organization have effective arrangements to communicate with customers regarding product information, enquiries/orders and customer feedback?***

E.2.1   The satisfaction of customers does not only depend on the quality of the final product or service, but also on the proper communication between you and your customers. Sometimes, even if the product is good, a poor communication can result in dissatisfied customers.

Therefore, it should be decided who has the responsibility and authority in your organization to communicate with customers at all stages, i.e. prior to, during and after execution of each customer order. There should be proper arrangement of communication with the customer for at least the following:

- Who provides product information to the customer, and how it is provided? How does the organization ensure that this product information is correct and current? Information about your product may be given through advertisements, website, product brochures, catalogues, specification sheet, tariff card (in case of a hotel), etc.

- Who in your organization should be contacted by the customers for quotations, orders, amendments to customer orders and also during product delivery, post-delivery, etc.

- By whom and how is customer feedback received and handled? This includes both planned feedback (for example, customer surveys), and unplanned feedback (for example, customer complaints).

Your system for communicating with customers needs to be readily available to them. Many organisations list special telephone numbers, website and email address to facilitate customer calls/enquiries. Another example is to make use of call centres.

Q.2.2   ***Does your organization always determine the exact details of the product/services needed by the customer including post-delivery requirements?***

E.2.2   For you to be able to provide a product that meets the customer's needs and expectations, it is necessary to know exactly what the customer's requirements for the product are, as well as the applicable statutory/regulatory requirements and such other requirements which the customer does not know but are necessary for the specified or intended use of the product. Accordingly it is necessary to obtain/understand the following from customers:

(a) The requirements that are specified by the customer (usually in a customer order, specifications, drawings, etc). You should also find out the post- delivery requirements of the customer, if any, e.g. servicing of equipment after installation, disposal of unnecessary packaging, end-of-life product disposal requirements such as exchange schemes for consumer durable products), etc.

(b) The requirements not specified by the customer but necessary for the known or intended use of the product. For example, the use of special coatings on a component in order to prevent rust, provision of a built-in safety fuse in a consumer electrical appliance.

(c) Statutory and regulatory requirements, e.g. requirements imposed by regulatory agencies such as marking 'best before use date' on a processed food product.

(d) Other requirements determined by the organization (usually based on product/service performance expectations and other customer expectations such as luxury and convenience features, appearance, etc e.g. hotels providing complimentary pick up and drop of guests from/to airport/railway station, etc.).

Q.2.3 *Does your organization review the product requirements given by customers and resolve the ambiguities, if any?*

E.2.3 Your organization should ensure that you understand and can meet all requirements before promising the customer that the product or service can be provided. In order to avoid misunderstanding about what the customer wants (and expects), it is necessary to review all product-related requirements of the customer (refer E.2.2). As a minimum, all quotes/proposals sent to the customer and customer orders (and their subsequent amendments) received from the customer should be reviewed.

A request for quotation e.g. enquiry/tender that is received from a customer needs to be reviewed before a quotation is submitted to the customer. You must determine if

- The information from the customer is clear and specific;

- You have the ability to provide the requested product/service.

Once a quotation is provided to the customer and the customer places an order (acceptance of the quotation), the order and the quotation must be compared to determine if there are any differences between them. Any difference should be resolved with the customer before starting the production/service provision.

If the customer places an order without having been previously provided with a quotation (as is the case in many organizations with 'standard' products or services as advertised in brochures or catalogues or internet), the order still needs to be reviewed before it is accepted. For this you must determine if:

- The order is clear and specific;

- You have the capability (and capacity) to provide the requested product or service including its delivery period;

- When the customer uses your product catalogue (either the printed copy or as displayed by you on your web site) for placing orders, you should ensure that part numbers included in the catalogue and other details of the product such as price, delivery period, terms of sale, etc were reviewed and are correct and updated before printing the catalogue. Other aspects such as regulatory requirements, if applicable, should also have been considered when the product was designed and included in the catalogue.

Records of these reviews must be kept; the record can be as simple as a notation on the request for quotation or the order with the initials of the reviewer and the date. If the request for the quotation or order is not accepted or it needs clarification, follow-up actions must also be recorded.

For verbal orders, e.g. by telephone, it is important to confirm the order before acceptance. This can be done, for example, by reading it back to the customer or sending an email confirming the details of verbal order, etc. In general, verbal and electronic orders need to be recorded. For example, the details of a telephonic order may be recorded on an order pad or may be entered straight in a computer while receiving the telephonic order.

It is likely that once the order is accepted, the same may be changed by the customer later on. If this is the case, it should be clear how this change is to be handled. Many times the change only affects the quantity or date of delivery; however, in some cases, technical aspects of the order will change. The type and scope of review needed should be based on the nature of the change. Most organizations handle changes in the same way as a new order. In any case, all changes must be agreed to with the customer and communicated to all individuals in your organization who have to implement the change. Typically, the purchasing department, the production scheduling department, the production department, dispatch departments should be informed of the changed requirements.

B. Design and Development

Q.2.4 **Does your organization prepare a design and/or development plan for designing the product and/or service you sell?**

E.2.4 Your organization will need to prepare a design and development plan. This plan should list down all the steps involved in the design process. Against each of these steps you should determine the following:

- Information needed including its sources;

- The resources required;

- The interfaces needed with other activities;

- The persons responsible;

- Review, verification and validation as appropriate;

- The output of this step;

- The time frame in which the step should be completed.

Design review, verification and validation may either be planned to be carried out separately or in any combination as suitable for your product. For example, prototype testing and evaluation of test results may provide information or both design verification and validation.

The design plan may be written in various formats depending on the requirements of the organization. It may be in the form of a control plan or a checklist. For example, a design plan for a new computer chip might be a large document while the plan for the development of a minor change to an existing product design might be as simple as an internal memo or a note.

Some design projects take a long time to complete and the plans may change for many reasons. Therefore plans should be updated to reflect the changes.

Q.2.5 **Does your organization before preparing a design and/or developing a product, determine inputs relating to product requirements?**

E.2.5 All product requirements before preparing the design of the product should be identified, for example the following:

- Customer requirements for the product;

- Functional requirements of the product;

- Product performance requirements;

- Product information from industry standards and national/international standards;

- Statutory and regulatory requirements for the product;

- Environmental requirements as applicable;

- Information from similar designs or previous designs;

- Safety requirements;

- Cost considerations;

- Product disposal requirements;

- Packaging and handling requirements;

- Servicing, maintainability, standardization and interchangeability requirements;

- Any other input that will help in the design process such as raw material availability, etc.

All information collected as input for the design should be reviewed, as you need to make sure that the information is clear, unambiguous and complete. Records of all the design inputs used should be maintained.

Q.2.6 **Does your organization ensure that the design and/or development output clearly defines characteristics of the product?**

E.2.6 The design outputs must describe characteristics that are essential for use and functionality of the product or service. The output from each design/development stage must be in a form that allows verification that all the input requirements to that stage have been met. The acceptance criteria (e.g. tolerance on the product characteristics) must be shown or referenced, and any limitations or restrictions that could affect operability of the product should be described. Appropriate approval is required for release of a design output and should be based on the roles and responsibilities defined during the design and development planning processes.

The design and development outputs should also include details for the preservation of the product i.e. information regarding product packaging or handling should also be an important output of the design and development process in order to ensure that the product is not damaged during delivery to its intended point of use, e.g. defining temperature at which the product should be stored/transported in order to avoid its deterioration.

Examples of design outputs include product specifications, drawings, methods of test, acceptance criteria, bill of materials, raw material specifications, packaging specifications, etc for manufacturing items, sketches/patterns for garments, recipes for food items, etc.

Q.2.7 **Does your organization review the design and/or development at suitable stages?**

E.2.7 Design and development review is a check to determine if the design and development activities are on track. More specifically you will need to verify if the design is adequate in meeting customer and other requirements (design and development input). For a simple design it may be sufficient to have only one design review at the end of the design process; however, performing only one design review may be very risky for more complex designs. A timely design review can prevent problems in a later stage. During design review all relevant persons/parties should be involved, including concerned internal departments/functions, as well as customers and subcontractors.

The results of the design reviews, including any problems that were identified and how they were resolved must be recorded. Complex designs may be reviewed in a formal meeting, and the minutes of this meeting may, inter alia, constitute the design review record.

Q.2.8 **Does your organization carry out design and/or development verification to check if design output meets the design input requirements?**

E.2.8 Design verification is one of the tools used by designers to determine if design input requirements are satisfactorily met by the design output. This verification is done before the design is released for production. The design verification activity is required to be carried out in a planned manner.

Design verification is done as per methods identified at the design planning stage. Various methods can be used for this purpose. Some of these are:

- Perform alternate calculations to check if original calculations are correct

This should be done by an independent person who was not originally involved for preparing the design. This method is generally used for verifying civil and structural designs, bridge designs, auto parts design and various other mechanical designs.

- Compare the new design with a similar or proven design

When the organization has long experience in dealing with items covered by the design or when it has got access to design of products or services of similar nature, comparison of

designs may be undertaken with a similar proven design. Variations found, if any, should be examined and modifications made to the original design as appropriate.

- Check all design documents independently for accuracy

The design documents could be independently verified by another agency to establish the accuracy of the design. In the case of civil designs, normally your customer will request this before using the design.

- Test the prototype product based on the new design

Prototype models are prepared by using the new design and subjected to qualification tests to determine the efficacy of the design, e.g. isometric model of a residential flat can be prepared by using CAD (computer-aided design).

Design verification will ensure that any mistakes and weakness in the design will be revealed and corrections can be made before finalizing the design. Records of all verification activities should be maintained, as they are important data for future designs also.

Q.2.9 **_Does your organization carry out validation of design and/or development to check if the product/service will meet the intended purpose?_**

E.2.9 Validation is the process of checking that the final product meets the customer and/or end-user requirements when used in the intended environment, i.e. actual condition of its use.

During validation prototypes of the product are subjected to tests in actual working conditions and results monitored to determine if product will meet specified requirements of use. Validation is the final stage in the design and/or development process and is an important opportunity to make changes in the design, if it is found after validation that the product does not meet customer and other requirements. Validation prior to release for production/construction may not be possible in many cases like structures, bridges, buildings etc.

In cases where validation is a very lengthy process, simulated or accelerated testing could be employed. In case of software the design is validated while in use by the customer and feedback obtained on an ongoing basis. In the case of the footwear industry where customer needs keep changing very frequently, it may not be possible to validate all new designs.

Type tests carried out on products are acceptable as validation. Examples of this are in the electrical industry where products are type tested in the laboratory under actual use conditions to validate the product, e.g. subjecting a control switch for 'n' number of times under simulated environment. Another example for electroplated components is keeping the electroplated item for 'n' number of hours in a salt spray chamber and then examining the condition of its plating after completion of test.

Records of all validation activities need to be maintained.

Q.2.10 *Does your design and/or development process provide for the control and approval of design changes and the management of these modifications?*

E.2.10 Design changes can occur at any stage in the design process. Such changes can occur as a result of customer changing the requirements, changes in the regulatory requirements, problems encountered in procurement or during manufacturing the product as per given design etc. Sometimes during the design process itself (e.g. as a result of design review, design verification or design validation) need for changes in design may come up.

Any change in the design should be controlled by following all necessary steps of the design process and such changes must be approved by an authorized person before implementation of changes. Sometimes small changes over time can result in a significant change in the design of the product. Such design changes should be validated to confirm that they continue to meet the new or original needs of the customer.

For complex projects or for software development, a change in one component part may have far reaching effects on the project/software as a whole. The impact of such changes needs to be carefully evaluated.

C. Purchasing

Q.2.11 *Have you evaluated your suppliers to decide if they are capable of meeting quality requirements for product and services which you intend to purchase from them?*

E.2.11 You may be doing an excellent job of controlling your own activities, but if your suppliers are not performing satisfactorily, you and your customers may be adversely affected. It is therefore important that your suppliers are reliable and exercise some form of quality control. Obviously not all suppliers are equally important. The standard requires more attention to be paid to those suppliers and purchased products/services that have more impact on the quality of your final product/services. Therefore you will need to:

- Identify which materials/components and services that you buy are critical for the quality of your final product/service;

- Define specifications of materials/components/services to be purchased;

- Establish criteria for the evaluation and selection of supplies. For example, many organizations require their suppliers to have an appropriate Quality Management System;

- Define a system for on-going supplier monitoring and periodic re-evaluation of suppliers to determine if improvement or other action is needed. For example, you can analyse your incoming product inspection data and data relating to promised vs. actual delivery period and also information relating to service/support provided by the supplier after delivery etc for evaluating performance of your suppliers.

You should keep records of evaluation of suppliers and any action arising out of it.

Q.2.12 *Do you have a process to check the adequacy of information contained in purchase orders before you release the same to the suppliers?*

E.2.12 While it is important that you should be clear in ordering what you want, it is equally important not to give unnecessary details in purchase order. For example rather than describing all the details of a product, it is often better to limit its details in the purchase order by simply mentioning the catalogue number (as long as this is a unique number and the supplier has the correct catalogue). Your purchase order should at least include the following:

- Technical description of the product which could be in the form of a product catalogue no., specifications, drawings, etc.;

- Packaging specifications;

- Quantity ordered;

- Delivery schedule;

- Place of delivery;

- Method and location for verification/inspection of material;

- Supplier's quality system details, if needed.

If you choose to place a verbal order with a supplier, you will need to keep a record of what was ordered. This enables you to verify whether you are actually getting what was asked for. In all cases, it is the intent of this requirement to avoid misunderstanding between supplier and you.

In any case the purchasing information (in the form of a purchase order) being sent to the supplier should be checked for its correctness. This check may be done by the person heading the purchasing function or by any other authorised person with inputs from quality or other technical personnel.

Q.2.13 **_Do you have a process to verify/inspect the products you receive from your suppliers?_**

E. 2.13 You need to ensure that the product or service you receive from your supplier meets your requirements. For this you may use any of the following options or others as you need.

- You can rely on your supplier's quality assurance system and accept materials without further checks at your end. However, for each lot of material, you may ask your supplier to send you the test data and statistical process control records.

- Sampling or 100% inspection/testing can be carried out on receipt of material at your end.

- Inspection at suppliers' location before dispatch from suppliers' premises.

- Engaging a third-party inspection agency to carry out inspection at supplier's premises before dispatch to you.

If you or your customers want to verify purchased product at the premises of the supplier, then you need to clearly inform the supplier about what is going to be verified and how and by whom it is going to be verified.

Q.2.14 **_Is your organization outsourcing some of its processes and do you exercise control over such outsourced processes?_**

E.2.14 While purchasing product and services from suppliers you are not outsourcing or sub contracting. It is simply buying product and services. An outsourced process is the one which is managed by an external party/other organization on your behalf or managed by some other function within your organization which is not in your scope of QMS. Such outsourced activity may be provided within your premises or at an independent site (e.g. an external machine/equipment maintenance agency operating from your organization to perform maintenance of your machines/equipment). Example of outsourced processes include getting painting or electroplating on some of your components done from an outside organization, getting IT/ housekeeping/ training services from external agencies, using a consultant for conducting periodic internal audit of your QMS, hiring a third-party inspection agency for inspection of incoming raw materials/components, etc.

Reasons for outsourcing may either be that you have the capability but do not want to invest your resources for such activities or you do not have the capability and therefore need the help of a reliable and competent organization.

The standard requires you to identify outsourced processes in your system description e.g. in your Quality Manual, and also describe how you manage these processes.

The control on outsourced processed will normally be subject to requirements of both clauses 7.4 (Purchasing) and 4.1 (General Requirements).

D. Production and Service Provision

Q.2.15 *Does your organization carry out production and service delivery under controlled conditions?*

E.2.15 You should carry out your production/service delivery processes under the following control conditions:

- Information giving full details of the product characteristics like dimensions, finish, shape, etc. should be available. In case of manufacturing industry, for example, this may be in the form of a specification sheet and/or drawing of the component to be made.

- In order to carry out the production activities, wherever necessary, the workers will need to be provided with suitable work instructions to tell them what to do and when. For example, in routine operations such as serving food in a fast food restaurant, workers do not need written instructions telling them what work to do and when to do, because this has been conveyed to them during their training.

- The equipment selected to produce the product should be capable of achieving the desired accuracy which means that the equipment is capable of achieving the dimensions within the given tolerances. This will also mean that the equipment be suitably maintained, for example through routine maintenance (daily cleaning, oiling, adjustments, etc.) and preventive maintenance (internal cleaning, internal adjustments, replacement of worn out parts, etc.).

- Measurement of the process is a key factor in controlling it. This will mean providing the instruments required to measure the product parameters and also for monitoring process performance. For example, in case of storage of food products in a cold storage of freezer, there will be a temperature indicating device fitted near the entrance of the storage and, before using the product taken out of cold storage, its temperature may be again measured by a probe thermometer.

- Monitoring and measurement of processes and products may be carried out as defined in the quality plan. For example, by using a control chart, you can find out if certain parameter of the product is within the pre-determined control limits. Product measurement will mainly relate to dimensions, fit, finish, etc. Process measurement will relate to temperature, pressure, speed, feed time, etc.

- Checking that the product meets all requirements and can be released to the next process or sent to the customer is known as releasing the product for delivery. This is usually known as pre-delivery inspection or final inspection. Once released the product may be packed as per specification and delivered to the customer. Delivery of a product includes activities like proper packaging, handling and shipment to customer. It must be ensured that these activities are carried out in such a manner that product reaches the customer in conforming condition.

Post delivery activities are those that are performed after the product reaches the customer. These include installation, servicing, technical support, warranty servicing, maintenance support etc. as agreed with the customer in the contract. These activities are also carried out under controlled conditions as stated above.

Q.2.16 *Does your organization need to validate (qualify) such process(es) where the deficiency in the product of such process(es) only becomes known when the product is in use?*

E.2.16 Verification/inspection of product before it is provided to the customer is a valuable opportunity to prevent delivery of defective product. However, sometimes it is not possible to fully verify the quality of the product without using or destroying it. For example, it is not possible to fully verify the strength of a weld or durability of paint on an item unless a destructive test is performed or the product is actually used. Similarly, for many service industries, the service provided is instantaneous, which does not readily allow verification before delivery of that service. For example, a lawyer who defends a client in court is obviously not able to verify his services before delivery. Failure to represent the client correctly will only be known when the judgment is delivered. All such processes are generally called special processes which will require validation.

For validating your production processes, it will first be necessary for you to examine your processes whose resulting product cannot be measured easily or without destroying the product. These processes will need validation which means that such processes are performed with the following controls as applicable.

- Defining qualification of personnel who will operate the process, e.g. welders will require a certificate for pressure vessel welding.

- Approval of equipment that will be used for the process. The equipment should be capable of meeting/achieving the process conditions/parameters repeatedly, e.g. capacity, accuracy, etc. of equipment.

- Availability and use of procedures detailing the methods to be used for carrying out the process and the parameters to be checked. For example, during welding current and voltage are critical parameters and during painting pressure, viscosity of paint, etc. are critical parameters.

- Determining what records will be maintained and what data are to be recorded which will give confidence that the process parameters have been followed.

- The criteria to be used for approval of the process namely the destructive test on a sample of the product to be carried out during approval stages that will tell us that the end product meets requirements.

- Revalidate the process if any of the above parameters are changed.

Q.2.17 **Does your organization need to identify its products, maintain their inspection/test status and keep traceability right through the incoming to delivery stages of the product?**

E.2.17 You may need to identify your products/services. Such identification can relate to the product (type, make, model, etc.) and to the inspection status (ok, reject, under review, under test, etc.). Furthermore, if you need to recall your product at a future date, then it needs to be identified with respect to the batch or lot of production (batch number, date of manufacture, etc.).

Product identification is needed when similar products are being processed and mix up needs to be avoided. Product identification can be done in many ways, for example:

- Route cards that accompany the product throughout the process;

- Tags/labels indicating the model, part number, operation no. etc.;

- Marking on the product by marker, paint, etc. (e.g. document in a courier company).

Identification may not be necessary in many situations (e.g. chemical industry where the process is continuous and the sequence of operations ensures mix up does not occur).

In order to avoid mix up of 'not OK' products with 'OK' products, you should identify the products with inspection status for determining whether a product has been accepted or rejected after the completion of inspection/test. For example, inspection status can be identified through:

- Tags – OK, not OK, under inspection, reject/review, etc. or

- Coloured bins – different coloured bins for each status e.g. green for OK, yellow for hold and red for reject or marking such colour codes on the floor where products are temporarily stored or

- By indicating the same in the test report

For example, in a hotel the status of a room after a guest has checked out is indicated by 'Not ready' sign. Once room service has cleaned the room and changed the linen etc, status is changed to 'Ready' and same is conveyed to reception. In a garment industry a batch of dyed lot of textile is identified suitably to ensure colour matching.

Maintaining traceability of the product is found to be useful in many industries so that in the event of a customer complaint the cause of the same could be traced. Sometimes the

customer may ask to demonstrate traceability of the product to a certain extent. Traceability will also be useful when a product needs to be recalled from the market or from customer(s) due to any reason (e.g. failure of a part in an automobile, defective medicine due to adverse reactions on a patient, etc.). For traceability purposes the records should be able to connect a batch of product with the date of manufacturing, the batch of raw material used for making the product, inspection/test details, etc. The records should also indicate the customer to whom the particular batch of product has been delivered for ease of recall.

Identification and traceability are necessary for many products. Generally it is a regulatory requirement for those products and/or services that can affect the consumer health and safety. For example, regulations may require that food and medicinal products have code or batch identification so that, if a problem is found after delivery, the faulty product lots can be located and, if necessary, the same can be withdrawn from use.

Q.2.18 ***Does your organization exercise due care on customer property either for use or for incorporation in your product?***

E.2.18 Any product, material or tool that belongs to the customer and has been provided to you by your customer for use or for incorporating in the product is called customer property. Examples of customer property are:

- Raw material, parts, sub assemblies, etc. given by the customer for incorporating into your product;
- Drawings, technical specifications, standards etc. given by your customer for use for design, manufacture or installation of the product;
- Software provided by the customer for use in processing customer data;
- Fabric given to a tailor for stitching garments or cloths given to a dry cleaner for washing;
- Film roll given to processor to develop and print the photographs;
- Motor vehicle given to repair/service center;
- Financial details (mortgage deeds) given by customer to a finance firm for obtaining loans etc.;
- Tools and equipment provided by the customer for use during installation or servicing of the equipment.

In the event you use any customer property, you should identify and verify the same, e.g. through inspection, before use. It should also be protected and safeguarded. If it is lost or damaged, the same should be recorded and the customer should be informed.

Q.2.19 ***Does your organization handle its products with care, both during internal processing and during delivery to customer?***

E.2.19 For preserving the quality of your product you may use identification, proper handling, packaging, storage and protection of your product. The nature and extent of such controls will depend on the kind of product involved. The purpose is that your product should remain conforming till it is delivered to your next process or to the customer. Let us look at each of the above individual activity and understand what is needed.

Identification: To avoid mix up, conforming products should be suitably identified throughout the processing till they are delivered to the customer. For example, this could be done by using tags, labels, stickers, coloured bins, markings on the product, etc.

Handling: Products should be handled in such a manner that they remain conforming. Delicate material like glass should be handled carefully, chemicals and pharmaceuticals should be handled using protective clothing to avoid contamination, sterile material should be handled using gloves, electronic equipment should be handled using special gloves to avoid build up of electrostatic charge, liquids should be handled in containers that are suitable for the purpose to avoid spillage and containers should be cleaned properly when a new liquid has to be filled to avoid contamination.

Packaging: Should be appropriate for the product. Glass products should be packaged in shock/impact absorbing material like foam or thermo cole. Chemicals should be packed in non corrosive material like glass, stainless steel, plastic containers etc. Food products should be packed in food grade packaging material.

Storage: All products should be stored in such a way so as to avoid deterioration during storage. For example, food products need to be stored at different temperatures, e.g. ice cream at –20 deg C, chocolates at 0 to 10 deg C. Electronic items need to be stored in dust free conditions, medicines in cool dry conditions, magnetic tapes and hard discs in non-magnetic environment, etc.

Protection: Products should be protected from various environmental conditions till they reach the customer. For example, covering the product suitably to prevent deterioration, food products protected by nitrogen (inert gas) atmosphere within the packet, some products covered with shrink wrap film, etc.

Q.2.20 *If monitoring and/or measuring equipment are used by your organization, do you ensure that their accuracy is maintained?*

E.2.20 Monitoring normally means supervision and observation activities using appropriate monitoring devices. Monitoring devices normally deliver non-quantitative results and are not usually calibrated but validated. For example a service organization like employment agency will generally not have any measuring equipment but could have monitoring devices, which could need to be validated.

Measurement normally means determining magnitude, dimensions, quantity or other such parameters using appropriate measuring equipment. Measuring devices (e.g. weighing scale, thermometer, micrometer, vernier, etc) normally give quantitative results and are usually calibrated for checking their accuracy.

You will first need to determine the parameters that should be monitored and measured during the product realization stage. Furthermore, you should decide the methods of measurement and devices/equipment to be used for measurement.

You should first determine measuring equipment which is to be used for checking conformity of product requirements and how these will be calibrated, identified, stored, handled so that their accuracy is maintained during the period of their use. If measuring equipment is to be used for indication purpose only, then it may not be necessary to calibrate them but they may be periodically verified only. Therefore it is necessary for you to decide which equipment needs calibration and which needs verification only or both based on their nature of usage.

Calibration means comparing your measuring equipment against standard equipment which is of a higher accuracy to determine how accurate your equipment is and deciding whether it is capable of making measurements with the accuracy required for job / parameter to be measured. Calibration process requires the following:

- Calibration should be done on a periodical basis based on the extent of use and also after any repair / maintenance of the equipment;
- The standard equipment used for calibration should have their calibration traceable to national or international standards and should be appropriate for the equipment being calibrated;
- All equipment that has been calibrated should be identified suitably to indicate their calibration status (e.g. through stickers, paint marks, small metal tags, etc);
- Once calibrated, equipment that does not need adjustments should be sealed from tampering / adjustments to maintain their calibration status;
- The measuring equipment should be stored in a way so as to avoid damage or deterioration of the equipment.

Calibration can also be done through external agencies that are authorized to provide such services.

During use, if it is found that the equipment is not working properly or its calibration status has been compromised, then you will need to assess the validity of previous measurements made with this equipment. This is to make sure that, if a product which has been checked with such equipment and has left your premises then you should take appropriate action to correct this situation, e.g. informing your customer or recalling the product from the market, etc. Certainly you will also immediately stop using this equipment till it has been verified / calibrated again.

Many measuring equipment these days are computerized and use various software for measuring certain parameters. These software need to be validated through suitable means to ensure that software is performing the tasks correctly. Most software have self-validating programmes and they need to be periodically run to ensure accuracy of the software and the equipment.

Records of calibration/validation should be maintained.

Part 3 − Measurement, Analysis and Improvement

Q.3.1 *Does your organization plan monitoring, measurement, analysis and improvement processes needed by your organization?*

E.3.1 Planning of monitoring, measurement, analysis and improvement processes means that these activities should not be left to chance. It is obvious that measurements made without a target value to compare results of measurement are measurements without a purpose.

You should plan how you intend to carry out the following monitoring and measuring activities for checking the effectiveness of processes:

(a) Processes needed to demonstrate conformity of the product.

This would cover Monitoring and Measurement of processes (8.2.3), Monitoring and Measurement of product (8.2.4), Verification of the purchased product (7.4.3) and Control of nonconforming product (8.3).

(b) Processes needed to check performance/effectiveness of the Quality Management System.

This would cover customer satisfaction (8.2.1) and Internal Audit (8.2.2.).

(c) Processes needed to continually improve effectiveness of the Quality Management System.

This would cover Data analysis (8.4.), Continual improvement (8.5.1), Corrective action (8.5.2) and Preventive action (8.5.3).

While planning the above processes the methods of monitoring, measurement, analysis and improvement should be defined including use of statistical techniques. Some of the problem-solving statistical techniques which could be used include Pareto analysis, histograms, correlation diagram, matrix analysis, etc.

Q.3.2 *Does your organization have a process to monitor, measure and analyse customer satisfaction?*

E.3.2 Clause 8.2.1 of the standard requires your organization "to monitor information relating to customer perception as to whether the organization has met customer requirements". The resulting information should be analysed to determine appropriate action.

The primary objective of QMS is to enhance customer satisfaction. The first relation with the customer starts through understanding his/her needs and expectations (both stated and implied). It is your contractual obligation to deliver goods and services that will meet every need of the customer and go a long way towards meeting all the preferences of the customer.

'Satisfaction' from the goods and services is the 'right' of the customer and therefore 'satisfaction' generally produces a neutral response from the customer. 'Dissatisfaction' may generate a variety of emotions and the most common may be, not to buy again. The opposite of 'dissatisfaction' is the 'surprise' or 'delight' where the customer's expectations are truly exceeded.

Some customers complain when their needs and expectations are not met while there are many who do not complain but may 'switch' to other suppliers. Therefore it is wrong to assume that those customers who have not complained are satisfied.

In order to monitor the customer perception you should:

- By using suitable method(s), carry out systematic checks on a periodic or continual basis to obtain the information on customer perception relating to goods and services supplied to them e.g. taking feedback from a guest who is checking out from a hotel, comparing your inspection results with those carried out by the customer on receipt of products at their end.

- By using suitable method(s), analyze the above information to check that what was promised to the customer has been provided or not.

- Use the result of analysis (preferably quantifiable) of the above information either for taking corrective actions (if you have failed to fully meet customer requirements) or making improvements (by using customer suggestions).

It is not sufficient that you only monitor the customer perception of the immediate customer in your supply chain but also go further and monitor perception of others in the supply chain as well. For example, if you are a manufacturer, you might sell to wholesalers, who then sell to retailers, who then sell to the general public. Thus you have three types of customers and they all have different requirements. For your products and services to sell successfully, you will need to satisfy all of them.

There are several ways of finding out what your customers think of you, for example:

- After delivery of product make telephone calls to the customers or make telephone calls periodically to regular customers;

- Use suitable questionnaires to obtain customer feedback. This is generally used in restaurants, hotels, airlines, hospitals and other services where there is direct interface with customers;

- Interview some of your customers by using a prepared checklist;

- Verbal feedback or compliments received by the personnel who are in contact with customers.

In addition to the above there is some information already available with you, which when analyzed, will give an indication of customer satisfaction, for example;

- Number of repeat orders received from the same customer;

- New customers referred to you by old customers;

- Trends of customer complaints i.e. upward or downward trend;

- Monitoring of lost business with your existing customers;

- Monitoring of warranty claims.

It is expected that, by obtaining and analyzing information from the customers and also by analyzing and using already available information with you, it would be possible to make a judgment about performance of your QMS. Needless to mention that the 'customer' is the real 'opinion maker' of your product and system and his/her assessment should be honoured and acted upon in such a manner that you achieve higher and higher patronage from your customers.

Q.3.3 *Has your organization effectively implemented the procedure for internal QMS audits?*

E.3.3   Internal audits are necessary to keep the Quality Management System on track. Quality is not just the responsibility of only a few persons; everyone has a role to play. Unfortunately, over time there is a tendency of the employees to ignore or drift away from the defined system. After internal audit it will be possible to find out how well employees are following the defined system e.g. procedures, work instructions, quality plan, quality objectives, etc.

You will need to write down and follow the internal audit procedure covering the following:

- Responsibilities and requirements for audit planning i.e. how and by whom the audits will be planned;

- Responsibilities and requirements for conduct of audit;

- Responsibilities and requirements for establishing records and reporting results of the audit.

Your management representative (MR) or any other manager can be made responsible for managing the internal audit function. Most organizations identify and train their employees to do inter-departmental audits as a part-time activity. In a small company where employees carry out multiple activities, it may not always be possible to find an independent person such that the person would not audit his/her own work area. In such cases the organization can take the help of QMS consultants who also provide audit services.

The internal quality audit process can be summarized as follows:

- Plan the audit indicating the work areas that will be audited, by whom and when;

- The appointed auditor will collect objective evidence by not only examining the old records but also by interviewing people, observing activities, and examining other relevant documents such as customer orders, product specifications/quality plans, etc.;

- Compare the gathered information with the system requirements and prepare audit findings (conformities, nonconformities, if any, and opportunities for improvements);

- Review the audit findings from previous audits;

- Prepare the audit report;

- Take corrective action by the concerned manager of the area audited;

- (Not by auditors);

- Verify the effectiveness of corrective action taken by the manager of the area (this can be done by the same auditor or by MR himself/herself).

As a part of management review your Top Management will look into the results of the internal audit to find out whether your QMS is working satisfactorily or not and is effective or not. (refer E.4.10).

Q.3.4   *Does your organization monitor and /or measure QMS processes to check if the processes are achieving targeted results?*

E.3.4   Monitoring and measurement of a process could be carried out in a number of ways, such as:

- As specified in the customer's order, e.g. at a construction site the ratio of cement and sand used is monitored by the customer's authorized representative;

- As per the instruction or procedure for monitoring of the process defined by you;

- As given in the inspection and test plan of the process.

For example, in case of mass production, statistical tools like control chart are used for monitoring processes. Whenever the defined characteristic of the process goes outside the control limits shown on the control chart, immediate action is taken to restore the situation.

In addition to monitoring processes as contained in the documents mentioned above it will be necessary to establish objectives for each process and targets should be fixed keeping in view the ability of the process to deliver the desired results. The following table gives some examples of the areas where targets could be fixed are

Process	Area
Sales and marketing	– Number of enquiries converted to customer orders – Response time to customer complaints, etc.
Purchasing	– Number of times the materials from suppliers were received as stipulated in purchase orders
Storage	– Instances of non-availability of materials due to lack of planning by store
Maintenance	– Average time between two breakdowns of the same machine
Training	– Number of times planned training completed as per schedule
Document control	– Instances of superseded documents (both internal and external) in use, etc.
Record control	– Instances of records not available in time – Instances of records not legible, etc.
Production and service provision processes	– Temperature, pressure, speed, etc. of the process – Customer waiting time for receiving service

Monitoring and measurement of processes is generally performed by the process operators. The process owners (managers) should be able to find the following after monitoring the process:

- Is the process performing as planned?

- Is the process achieving the results in the best way?

- Are the results being achieved meet the defined targets?

When a process parameter is found to be drifting outside the targets set, correction should be done to restore the situation followed by corrective action to eliminate the cause of the deviation.

Q.3.5 ***Does your organization carry out inspection and testing of product at various stages of production/service provision?***

E.3.5 In addition to the monitoring and measurement of processes given in clause 8.2.3 of the standard (refer E.3.4), it will also be necessary for you to check the product quality at various stages of production or service provision. The extent of such product inspection (monitoring and measurement) would depend upon the level of controls exercised over the processes. For example, in the process industry (say milk processing) due to online or regular monitoring of process parameters, the frequency of product testing is low while in case of the engineering industry (say machining operation) the product is intermittently checked for dimensional control.

During inspection of the product various characteristics of the product viz dimensions, workmanship, hardness, tensile strength, chemical composition, etc., in case of manufactured products and accuracy of transaction, response time to customer queries, taste of the food, right placement of crockery and other items on a dining table in a restaurant, etc in case of service provision would need to be monitored and measured at various stages of product and service realization.

For ensuring that all required characteristics of the product are checked, you should draw up a product testing plan giving:

- Characteristics with their specifications to be checked at each step;

- Test method and test equipment, if any, to be used;

- Number of samples to be inspected/tested;

- Persons responsible for inspection/ testing;

- Action to be taken when a nonconformity is detected;

- Method and format of recording the inspection and test results.

The following table gives an example of part of a quality plan for milk powder:

Process step	Inspection/test	Frequency	Responsibility	Specification
Mixing	Total solid	One sample per mix	Operator	45%-55%
	pH	One sample per mix	Operator	6.2-7
Spray drying	Bulk density	One hour after start of drying	Laboratory	0.45-0.55g/ml
	Moisture	Every hour	Automatic/Operator	4.5% max.

You should have a system of keeping the necessary monitoring and measurement records or have other means of showing that inspections have taken place. You should also have a clear procedure for release of product to the next stage or for final dispatch to your customer. Such release should have evidence that the release has been made by the authorized person.

You should ensure that before release of product to the next stage of production or before dispatch to the customer, all planned inspection and testing have been completed as described in the test plan mentioned above. In the event of any departure from this test plan, necessary approval for such deviation should be given by your authorized person or from the customer, if the contract with the customer has a condition for such prior approval.

Q.3.6 **_Does your organization effectively control the nonconforming product so that it is not unintentionally used or delivered to the customer?_**

E.3.6 Non-fulfillment of a specified requirement is termed as nonconformity. This may happen in a product or service, anywhere during the product realization process. It is, therefore, essential for you to ensure that such nonconforming product (defective) is not used or dispatched to the customer. This is also applicable to internal processes where the output from one process goes as input to the next process. To avoid this from happening the first thing is to identify the nonconforming product (not OK) and segregate it from other conforming products (OK) to ensure there is no mix- up.

You should prepare a document describing the procedure for dealing with nonconforming product, along with the responsibility and authority of your person for its disposal in one or more of the following ways:

(a) By taking up repair or rework of the product to make it conforming (OK) to specifications. Such reworked or repaired product should be checked again to verify its conformity.

(b) For example: A pesticide formulation was found to contain less active chemical than what was required in the specification. The same can be reformulated to bring the technical content to the specification.

(c) Releasing the product with concession in consultation with the customer or designated authority, wherever applicable.

(d) Regarding the product to another application based on its suitability of use. For example: A precision meter with a specified accuracy level of + or − 1 % was found to be nonconforming as the accuracy level was found to be + or − 2%. Such meters can be released in the market for applications where requirement is + or − 2%.

(e) Rejecting/scrapping of the nonconforming product.

(f) If the nonconformity is found after delivery of the product to the customer, the effect of such nonconformity on the usage of the product by the customer should be reviewed by you. Depending on the severity of the impact, suitable actions including product recall may be initiated by the organization. For example: if a catering company discovers that it has inadvertently dispatched the processed meat that was past its 'use by date', it may immediately segregate and quarantine the product and if already delivered to the customer then recall the product as well.

You should maintain records of the nature of nonconformities and actions taken there on.

Q.3.7 ***Does your organization analyse data generated as a result of monitoring and measurement of processes and products to demonstrate effectiveness of QMS?***

E.3.7 In most organizations monitoring and measurement data (for example, process monitoring data, results of inspection and testing of product, customer complaints, internal/external audit results, etc.) is constantly collected. Unfortunately, in many cases the task is considered finished when this data is collected and kept in files. But thick files of data are of little use in themselves. This data becomes valuable if it is examined closely to see what underlying information it contains. Thus data is only valuable if it is analyzed and is actionable. Use of statistical tools like histograms, Pareto analysis, correlation diagrams, etc., are valuable tools which you can use for identifying trends, root causes of the problems etc, and use them for improving the effectiveness of the Quality Management System. For example, a complaint of 'wrong materials delivered' when analyzed may lead to possible causes such as inadequate identification of the materials and disorganized storage of material.

The analysis of data in the above manner will enable you to get the following information:

- The level of satisfaction amongst your customers;

- Extent to which your product and/or service conforms to the specified requirements;

- Trends of key characteristics of the processes;

- Trends of key characteristics of the product;

- Trends of product quality received from the suppliers;

- Opportunities for preventive actions.

In addition to the above you can extend analysis of data to other areas as well depending upon the need.

Q.3.8   **_Does your organization continually improve its QMS?_**

E.3.8   One of the purposes of QMS as stated in the standard is that that the organization should "aim to enhance customer satisfaction through the effective application of the system including processes for the continual improvement of the system". Clause 8.5.1 Continual improvement, of the standard stipulates that you must continually improve the Quality Management System and this clause includes the following processes that can be used for initiating improvement of QMS:

- Commitment to continual improvement being a policy issue will remind all in the organization to work towards improving the system.

- Periodic review of the quality objectives and setting and achieving higher targets will demonstrate a measurable improvement.

- Each internal audit can bring out opportunities for improvement in the processes.

- Improvement projects can be identified by using results of analysis of data.

- Eliminating root causes of nonconformities in the products, processes and system can avoid their repetition, thus leading to improvement in product conformity, process conformity and system conformity.

- Past trend of processes, market survey data, suggestions from your employees, etc. can provide useful information for initiating preventive actions.

- Your Top Management after reviewing results of various processes and other data should give directions for initiating improvements in the product requirements as well as in QMS.

There are many tools and techniques described in the literature that can be used to make improvement in processes and systems. Some of the best techniques have evolved from the Total Quality Management movement. They emphasize involving employees at all levels, in the improvement processes recognizing that the people who do the job know more about it than anyone else in the organization.

Q.3.9 ***Does your organization take effective corrective actions needed to eliminate the root cause of deviations/problems?***

E.3.9 Corrective action is taken to prevent an existing problem from being repeated. Corrective action is often used to deal with product nonconformities but it goes beyond that and includes customer complaints, supplier problems, audit reports and all other situations such as process monitoring results that deviate from planned conditions.

The intent of this requirement is to have a disciplined approach to problem solving, i.e. identifying the root cause of the problem, and the potential costs/risks associated with it if no action to prevent its recurrence is taken, recording the results of the action taken and verifying that it was effective.

Corrective actions are not effective when they do not achieve the desired results i.e. the action taken does not prevent the recurrence of the same problem. If the corrective action relates to the changes to be made in the instructional documents, then necessary amendments should be made in the work instructions/procedures/methods of test/specifications/quality plans, etc or included it in the future training topics so that it becomes the practice. For example, if a customer complaint is received about damage of product during shipment, the immediate action taken will be to provide replacement of the product to the customer. In this case 'corrective action' would include first analysing 'why' such damage has happened. The analysis may result in possible 'corrective actions' such as 'change of design of packaging' or 'increased supervision during packing' or 'training of packers' or their combination.

There is a popular Japanese way for looking at the quality-related problems i.e. saying that 40% of such problems are due to inappropriate design/product specifications, 30% are due to wrong purchasing of raw materials/components and remaining 30% may be related to production activities. This gives a message that, while searching root causes, you should also examine areas other than production to investigate all the possible root causes. Thereafter action should be taken to eliminate them.

An effective corrective action process will provide continual improvement of QMS. Status of corrective actions is reviewed by Top Management along with other items of agenda of periodic management review of the QMS (refer E.4.10).

Q.3.10 ***Does your organization take effective preventive actions to prevent potential problems that can result in unnecessary cost and dissatisfied customers?***

E.3.10 Preventive action is taken to prevent a potential problem from occurring in the first place. It is one of the improvement tools in the Quality Management System. Problems that can affect business results, product conformity, process performance, customer satisfaction and the Quality Management System must be prevented to the greatest extent possible. Sometimes the management is usually so busy dealing with current problems (popularly called fire fighting) that they do not have the time or even know where to look for potential problems.

Preventive actions are usually handled in the same way as corrective actions, just with a different 'focus', i.e. 'potential problem' instead of 'existing problem'. This involves finding the cause of the potential problem or failure, recording the anticipated results of the action taken and verifying that the action was effective.

The intent of this requirement is to have a disciplined approach to risk analysis (i.e. identifying the root cause of the potential problem and the potential costs/risks associated with taking no action to prevent its occurrence).

Opportunities for preventive action may come from customer feedback information, suggestions from your own employees or by analyzing available information such as product inspection reports, data relating to process performance, machine down time, scrap and rework rate, etc. Preventive actions would require analysis of available data or other benchmark data from outside the organization. Continuing with the example given in E.3.9, if the packaging design is tested under different shipment conditions before using the packages and then instructions are prepared

for the packers, such action would be called preventive action. Generally preventive actions are taken at the design and/or planning stage itself.

Some more examples where preventive action may be applied are:

- Feedback and suggestions from employees indicating the need for more efficient process for service delivery;

- Process giving early warning of likely out of control limits through alarms and indicators.

An effective preventive action process will provide continual improvement of QMS. Status of preventive actions is reviewed by Top Management along with other items of agenda of periodic management review of the QMS (refer E.4.10).

Part 4 – Documentation and Implementation of QMS

Q.4.1 **Has your Top Management taken a considered decision for implementing ISO 9001 for organizational benefit?**

E.4. 1 Certification to ISO 9001 since its first publication in 1987 is becoming more popular every year. World over by end of 2009 over a million certificates have been issued in 178 countries. In many forums the credibility of ISO 9001 certification is being debated. Majority of the enterprises have perhaps taken certification only to use it as a publicity tool. In the process they are incurring extra costs for maintaining the certification without the latter helping them to improve their market share as a result of increased customer satisfaction (which is the primary objective of ISO 9001).

In view of the above, your Top Management while deciding to undertake the development and implementation of a Quality Management System (QMS) should first be clear about the purpose for which the system is needed by your organization. If the only driver or goal is to get on customers' tender lists or have it because your competitor has already got it, there is a big danger that your QMS will just be a set of documents for getting certification only. The results obtained with such a strategy will not serve any useful purpose to you and will simply put a serious drain on your resources. Rather, your Top Management must first decide on specific objectives to be achieved through the QMS that will provide some tangible benefits to you such as:

- Maintaining and continually improving the quality of products and/or services for enhancing customer satisfaction;

- Providing better confidence to customers that your organization is capable of meeting their requirements consistently;

- Improving organizational performance and productivity, leading to cost savings.

With the above objectives in view, you will not only have a marketing edge but will also be a preferred supplier to your satisfied customers which means more business and thus more profits.

Q.4.2 **Is your organization aware of the steps involved in the systematic development of a QMS?**

E.4.2 Development of Quality Management System (QMS) in line with ISO 9001 for your organization should be handled as a project. For the successful completion of the project full commitment of Top Management will be necessary. They should first commit to provide timely resources for implementation of QMS.

A systematic way of implementing the QMS project will include the following steps:

1. Top management should decide about the purpose of establishing the QMS and the scope of QMS (refer E.4.1 and E.4.5);

2. Appoint a project leader who may subsequently act as management representative (refer E.1.6);

3. Appoint a QMS Implementation Project Team (if necessary);

4. Conduct a gap analysis to assess the extent to which the existing policies, procedures, work instructions and practices are in line with ISO 9001 and additional processes, if any, which will need to be set up in your organization;

5. Develop the required QMS documentation (refer E.4.5, E.4.6 and E.4.7);

6. Review and approve the QMS documentation (refer E.4.8);

7. Introduce and train all employees in "How to use your QMS" (refer E.1.8);

8. Practice the QMS for at least three months and maintain records (refer E.4.9);

9. Identify and train internal quality auditors (refer E.3.3);

10. Conduct the first series of internal audits (refer E.3.3);

11. Conduct a management review (refer E.4.10);

12. Initiate corrective and preventive actions (refer E.3.9 and E.3.10).

If you think you need help of a QMS consultant to assist you with the interpretation of the requirements of ISO 9001 you may appoint one. If your management wishes to obtain third-party certification, then select a Registrar/Certification body at an appropriate time, say during step 8. At an appropriate stage the selected certification body (CB) will first review your documents (quality manual, procedures and other documents developed by you). Thereafter once you have completed all activities satisfactorily (i.e. up to step 12 above), the CB will arrange audit of your QMS and based upon its results will issue the certificate to you.

It will be realistic to give a time frame of 9 to 12 months for completing all the above steps satisfactorily.

Q.4.3 ***Is your Top Management committed to implementing and continually improving effectiveness of the QMS?***

E.4.3 Commitment is an obligation that a person takes on in order to do something. Success of any quality initiative including QMS in an organization heavily depends upon the commitment and involvement of its Top Management. Accordingly there are certain roles and responsibilities stated in ISO 9001 which should be carried out by your top management in order to create an environment in the organization so that every employee is encouraged to achieve the defined objectives. For this at least the following actions are expected to be driven by Top Management:

- Communicating to the employees the importance of meeting the customer's needs and expectations including applicable statutory and regulatory requirements relating to the product;

- Establishing a Quality Policy that is appropriate for the purpose of the organization (refer E.1.2);

- Establishing measurable quality objectives at the organizational level and at departmental levels (refer E.1.3);

- Conducting periodic management reviews to assess the suitability and effectiveness of the QMS and deciding plans for its improvement (refer E.4.10);

- Provide necessary resources to maintain and improve the QMS (refer E.1.8, E.1.9 and E.1.10).

The commitment of Top Management is best visible if they start spending time on issues relating to product and system quality; listen to their staff and customers, motivating their staff to achieve performance standards, not permitting deviations from product specifications, etc. The commitment will also be evident from positive customer feedback, internal and external audits and sustained business growth.

Q.4.4 *Does your organization determine the processes, needed for the QMS and decide their interaction, including criteria for their effective operation and control?*

E.4.4 Before initiating implementation of the QMS, it is necessary first to decide which of the processes in your company are needed for QMS. Such processes will fall under the category of planning processes (such as establishing and communicating quality policy/objectives, defining responsibility and authority, etc), provision of resources (such as human resource development, provision and maintenance of equipment/software/utilities/support services, etc.), product realization or key business processes (such as marketing, sales, design and development, purchasing, production, storage, dispatch, etc,), measurement, analysis and improvement (process monitoring, stage and final inspection of product, monitoring of customer perception, internal audit, data analysis, corrective/preventive actions and improvement of QMS). It is quite likely that some of the product realization processes as stated above are not taking place in your organization and have not been outsourced. Therefore such processes will not become part of your QMS and will thus be excluded (refer E.4.5 for details).

The next step is to decide the sequence and interaction of the above processes i.e. what happens first and what happens next and at what stage support or information is needed from other processes.

Figure 2 gives an idea of sequence of processes (output of one process becomes input to next).
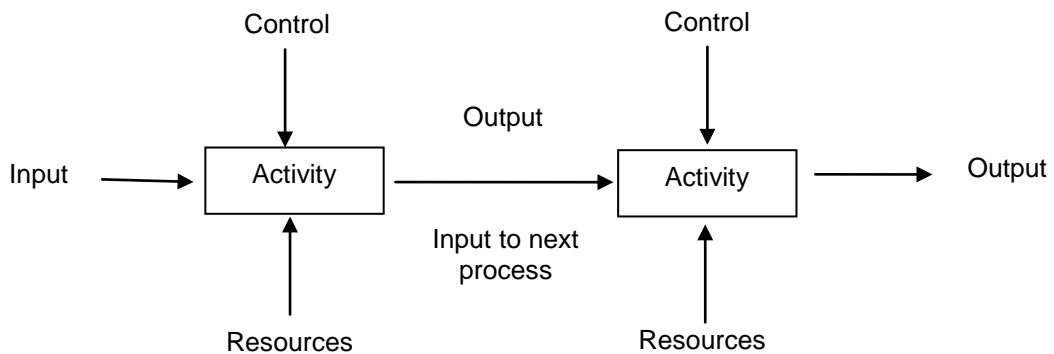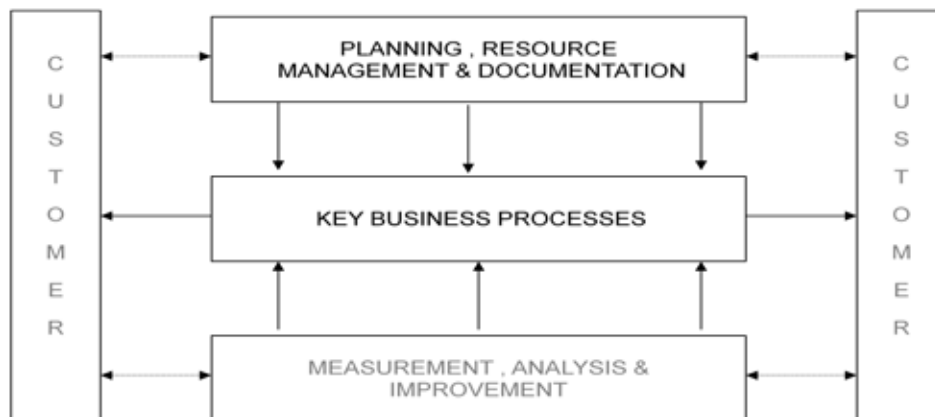
Figure 2 – Sequence of processes

Figure 3 shows the example interaction of the main processes of QMS.

Figure 3 – Interaction of processes

It is also necessary that for a process to be "effective" it must be achieving its intended objectives. Therefore you should define methods, criteria and objectives of the process and also define methods for gathering and monitoring data so that the same can be analyzed firstly to check if the defined objectives are being met and then initiate improvement actions.

Q.4.5 *Do you have a Quality Manual that describes the core elements of QMS and the interaction of various QMS processes?*

E.4.5 Clause 4.2.2. of ISO 9001 states that you should maintain a Quality Manual. The Quality Manual is a top level document that explains how you intend to address the requirements of ISO 9001 and may also provide reference to other documents of QMS.

The Quality Manual is a unique document for each organization in terms of structure, format, content and method of presentation. It usually includes a brief profile of the organization viz a brief background of the organization and also information about its products/services, production process, organization structure, job description of key personnel etc. The Quality Policy and related quality objectives are often included in the Quality Manual. The Quality Manual also includes:

- **The scope of the Quality Management System.**

  The scope of QMS here means those activities, products, locations to which the QMS applies. For example, scope could be expressed as "Design and manufacture of xyz product(s) at our factory located at ……' (This scope will be included in the certificate issued by the certification body).

- **The exclusions, if any, of permissible requirements of clause 7 Product realization, of the Standard and justification for the same.**

  This does not mean that you can discard any requirement in clause 7 just because you do not want to do it, or there is no regulatory requirement for the same. The standard (in clause 1.2) allows you to exclude only those requirements in clause 7 (and only in clause 7) which do not apply to your organization (i.e. you are not doing them) or may not apply to the products or services that you are providing, with the restriction that by excluding such requirement(s) the product and/or service quality will not be affected. For example, you could exclude the following:

  - You do not need to carry out design (7.3) because the same is given by your customer/collaborator, then you need not cover this process in your system.

- If you do not have any customer-supplied property, then you do not need to apply 7.5.4.

There may be circumstances where some specific requirements within one of the sub-clauses of clause 7 might need to be included while the rest of the requirements in that sub-clause could be excluded. For example, in 7.5.3, identification and traceability requirements may be considered for exclusion but not the requirement given in 7.5.3 regarding status with respect to monitoring and measurement.

In any case whatever you decide to exclude, you should provide adequate justification for the same in your quality manual. This justification should be acceptable to the certification body if you wish to obtain certification of your QMS.

- **Documented procedures or reference to them.**

A small organization may find it appropriate to include the description of its entire QMS, including all the documented procedures as listed in the standard and needed by you, within a single manual. Otherwise you have a choice to keep procedures in a separate procedure manual and refer to them in the Quality Manual.

- **The description of the interaction between the processes of the Quality Management System.**

    Refer E.4.4

The Quality Manual can be presented in any convenient format. It is a controlled document. It may be added here that your Quality Manual need not be a replica of ISO 9001 and should be written such that it remains user (employee) friendly within the organization.

The Quality Manual may also serve as a useful document for marketing purposes and can be shared with existing and prospective customers to build confidence in your QMS.

Q.4.6   *Do you have documented procedures for control of documents; control of records; internal audit; control of nonconforming product; corrective action; and preventive action that describe how these six processes and their related work activities are performed?*

E.4.6   ISO 9001 specifically states that documented procedures for the following processes should be prepared by the organization:

- Control of documents (4.2.3) (refer E.4.8);

- Control of records (4.2.4) (refer E.4.9);

- Internal audit (8.2.2) (refer E.3.3);

- Control of nonconforming product (8.3) (refer E.3.6);

- Corrective action (8.5.2) (refer E.3.9);

- Preventive action (8.5.3) (refer E.3.10).

These six documented procedures describe the above six key processes of your Quality Management System. Each of these six procedures should at least describe

- The scope of their application;

- The specific activities and/or tasks that need to be performed, why, when, where and how, as appropriate;

- Who is responsible for performing the activities and/or tasks in the process;

- The essential records that provide the required evidence of the activity having been done as per procedure.

Other procedures and/or work instructions if needed can also be compiled to describe the rest of the required Quality Management System processes and their related work activities (refer E.4.7). These procedures may take whatever form is most appropriate, including process flow charts, tables, text or a combination of them and may, of course, be presented on paper, in electronic format or a combination of them. They should be controlled (refer E.4.8) to ensure they are adequate, authorized and current.

Q.4.7   *Does your organization require documents and records other than the six mandatory documented procedures and 21 records as listed in the standard for ensuring effective, planning, operation and control of its processes?*

E. 4.7   ISO 9001 has given some minimum documentation requirements needed for setting up of a QMS, such as Quality Policy, Quality Objectives, Quality Manual and six system related procedures (refer E.4.6). Furthermore 21 records (refer E.4.9) are also listed in ISO 9001 which you will keep maintaining to demonstrate that the QMS continues functioning as designed in the above documents.

In addition to the above documents and records the standard provides that your organization can decide what additional documents are required for effective planning, operation and control of your processes. For example, you may need drawings, specifications, quality plans, work instructions, technical procedures, process flow diagrams, method of testing, instrument calibration procedures, etc. Furthermore you will also need, for example, external documents such as technical regulations, codes of practice/standards published by national/international standards bodies, machines/equipment maintenance manuals given by equipment suppliers, etc. Similarly you may also need to maintain additional records beyond the 21 records listed in the standard.

A word of caution may be added here that the primary objective of a QMS is to provide conforming products to customers. Over the years some organizations have forgotten this particular objective and have focussed their attention on producing excessive documentation and records, rather than, managing their processes to achieve the desired results.

Q.4.8   *Are your organization's documents kept under proper control as specified in your procedure on control of documents?*

E.4.8   All QMS related documents which include the following must be controlled:

- Documented statements of the Quality Policy and Quality Objectives;
- The Quality Manual;
- The six documented procedures;
- Other documents needed by the organization for effective planning, operations and control of processes e.g. quality plans, drawings, specifications procedures, work instructions, etc.);
- Documents of external origin provided by customers and others that are needed in the Quality Management System.

Your organization will need to develop a procedure for control of the above documents covering the following:

- Authority and method of approval of a new document or revised document;
- Authority and method of issue of approved documents;
- Periodicity and method of review of documents after updating;
- Authority for approval of updated or changed documents;
- Conventions for indicating current revision status e.g. Rev.01, Rev.02 with date, etc.;
- Conventions for indicating the changes in the documents e.g. sidelining, underlining, bolding, etc., of the changed text;

- Convention of identifying a document e.g. by numbering them by using alpha numerical digits, etc.;

- Responsibility and method of identification and distribution of external documents;

- Method of preventing use of obsolete documents e.g. withdrawal, destroying, marking the document as 'obsolete', indicating 'obsolete' in the master list of documents and method of retaining copy(ies) of obsolete documents for future reference.

The standard also requires that employees should have easy access to relevant versions of documents applicable to their work area.

Some organizations use their internal computer network (often called an INTRANET) to provide documents at the relevant work areas and to ensure that the current approved version is available quickly for use by all concerned. The soft version of documents, if used, should also be controlled to meet the above requirements.

Q.4. 9 ***Are all the necessary records created and controlled as described in your documented procedure on the control of records?***

E.4.9 ISO 9001 Clause 4.2.4 specifies that a documented procedure be prepared to control the records needed to provide evidence of conformity of the requirements given in the standard.

The following is a list with references to the requirements of ISO 9001 where records must be produced in an appropriate format, whether on paper or in a computer database:

SI	Clause	Record required
1	5.6.1	Management reviews conducted by top management
2	6.2.2 e)	Education, training, skills and experience of employees
3	7.1 d)	Evidence that the realization processes and resulting product fulfil requirements
4	7.2.2	Results of the review of requirements related to the product and actions arising from the review
5	7.3.2	Design and development inputs relating to product requirements
6	7.3.4	Results of design and development reviews and any necessary actions
7	7.3.5	Results of design and development verification and any necessary actions
8	7.3.6	Results of design and development validation and any necessary actions
9	7.3.7	Results of the review of design and development changes and any necessary actions
10	7.4.1	Results of supplier evaluations and any necessary actions arising from the evaluations
11	7.5.2	Records to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement
12	7.5.3	The unique identification of the product, where traceability is a requirement

13	7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use
14	7.6 a)	Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist
15	7.6	Evidence of validity of the previous measuring results when the measuring equipment is found not to conform to requirements
16	7.6	Results of calibration and verification of measuring equipment
17	8.2.2	Internal audit results and follow-up actions
18	8.2.4	Indication of the person(s) authorizing release of product.
19	8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
20	8.5.2	Results of corrective action
21	8.5.3	Results of preventive action

Some of the records listed above under sub-clauses of clause 7 above may not be necessary depending on the nature of the business and for which exclusion has been justified in the Quality Manual (refer E.4.5). For example you need not maintain five records listed at serial 5 to 9 above if you have excluded the design process since you do not design products/services. In addition to the above, if the organization wishes to maintain more records, it may do so. However, all the records should be controlled as per the procedure for control of records which should include the following:

• Convention of identifying the records e.g. numbering with a prefix "R";

• Method and place of storage, including storage of backup of soft version of records;

• Means of protecting the records from damage such as fire, flood, insects, etc, including use of antivirus software for protecting soft records;

• Methods and timeliness of retrieval of records;

• Retention period of records, keeping in view the organizational/contractual/regulatory requirements;

• Periodicity of review for destruction of records, including methods of disposal e.g. shredding, incineration, recycling, etc.

If the records are kept in soft versions the same would also require the above controls, including security of records.

Q.4.10 *Is your QMS reviewed by Top Management regularly and in a planned manner for assessing its suitability, adequacy and effectiveness?*

E.4.10 Your Top Management must review the organization's QMS on a regular and planned basis to ensure it is functioning effectively and continues to be suitable and adequate. Apart from reviewing the functioning of the system the review should also assess opportunities for improvement, identify weak areas and determine if any changes are needed to strengthen the system.

Management review meetings should not be used for discussing day-to-day problems. It should be used for discussing broader issues such as trends in the system, resource requirements, weak areas needing attention, etc. Management reviews should also be used for discussing long-term corrective actions and identify opportunities for preventive actions. The following information should at least be available for conducting a purposeful review by the top management.

- Extent of achievement of Quality Objectives;

- Internal and external audit results and action taken thereon;

- Feedback received from customers including complaints;

- Performance of the various processes of the QMS;

- Trends of product conformity, product nonconformities, customer returns/ rejections, etc.;

- Corrective and preventive actions in-hand and those completed;

- Improvement projects identified;

- Actions taken on the decisions of previous management reviews;

- Identified gaps in the resources viz human, facilities, equipment, etc.

The following decisions should be taken during the review along with the responsibility of the persons and timeframe for implementing the decisions.

(a) Actions to be taken to improve the effectiveness of the QMS.

(b) Actions to be taken to improve process performance.

(c) Actions to be taken to improve products, specifically in relation to customers' needs and expectations.

(d) Resources needed to improve the QMS.

(e) Action needed to implement changes, if any, made in the Quality Policy and Quality Objectives.

Records in the form of agenda and minutes of the meeting or any other format should be maintained.

By implementing decisions of management reviews you will be able to keep your QMS dynamic. Changes like internal changes in the working of the organizations, changes in the profile of customers/markets, hiring/transfer of people will also require review and modifications in the Quality Management System.

It is quite obvious that, for making an application for third-party certification (if you decide to have one), you should have evidence that the system has not only been audited internally but all the other data as listed above is available and has been reviewed and some improvements are in hand. For this it will be necessary to implement the system for at least a period of three months so that meaningful data is available for conducting a management review as above.

ASSESSMENT REPORTS

Part 1 – Planning and Resource Management

Take the total score obtained from filling in Questionnaire – Part 1 and check the assessment.

Score	Percentage	Maturity level	Assessment
0 to 10	0 to 20%	Lack of awareness	Your planning for QMS resources and commitment of top management are lacking. You will have to put a lot of effort and resources to meet the requirements.
11 to 20	21% to 40%	No formal approach	You are aware of the requirements of the QMS. You need to convert awareness into practice by implementing the requirements in a systematic manner.
21 to 40	41% to 80%	Formal system approach	You are in the right direction of putting in proper planning including resources needed to have an effective QMS. If your score is close to 40, then your planning and resource management is fully in place
41 to 50	81 to 100%	Improvement approach	You are doing very well as far as planning and resource requirements for QMS is concerned. This will help you to better manage your key business processes and ultimately achieve the purpose of QMS i.e. enhanced customer satisfaction.

Part 2 − Key Business Processes

Take the total score obtained from filling in the [Questionnaire – Part 2](#) and check the assessment.

Score	Percentage	Maturity level	Assessment
0 to 20	0 to 20%	Lack of awareness	You lack awareness about better ways of managing your key business processes.
21 to 40	21 to 40%	No formal approach	You are aware how the systematic control of business processes can affect the quality of your products and services. You need to use this awareness and start controlling your business processes as per the requirements of the standard.
41 to 80	41% to 80%	Formal system approach	You are in the right direction and managing your business processes well and, if your score is close to 80, then you have fully implemented the requirements relating to business processes as defined in the standard.
81 to 100	81% to 100%	Improvement approach	You are doing very well and, if you continue improving your business processes, you will be able to satisfy your customers better, resulting in more business and thus more profits.

Part 3 – Measurement, Analysis and Improvement

Take the total score obtained from filling in the Questionnaire – Part 3 and check the assessment

Score	Percentage	Maturity level	Assessment
0 to 10	0 to 20%	Lack of awareness	You lack awareness about the usefulness of collection and analysis of data and taking action on the results.
11 to 20	21% to 40%	No formal approach	You are randomly carrying out monitoring/measurement of your processes and product and, if some deviations or customer complaints arise, you only carry out corrections (fix the problem) and do not carry out corrective action.
21 to 40	41% to 80%	Formal system approach	You are on the right track and, if your total score is close to 40, it means that you are carrying out monitoring and measurements of processes and product in a planned manner, including monitoring of customer perception and carrying out periodic internal audits. The data so obtained is being analyzed and used for putting in effective corrective actions in such a manner that same deviation/problem/complaint is not repeated.
41 to 50	81 to 100%	Improvement approach	You are effectively using results of data analysis and audit findings and your Top Management is involved in deciding improvement of various QMS processes and providing resources for the same.

Part 4 − **Documentation and Implementation of QMS**

Take the total score obtained from filling in the Questionnaire – Part 4 and check the assessment

Score	Percentage	Maturity level	Assessment
0 to 10	0 to 20%	Lack of awareness	You are not aware about the quality manual, procedures, work instructions, records and other documents which are required to be maintained for implementation of a QMS.
11 to 20	21% to 40%	No formal approach	You have a random collection of some documents for controlling quality but not all those which are listed in the standard viz quality policy, quality objectives, quality manual, procedures, work instructions, records to provide evidence of functioning of a system, etc.
21 to 40	41% to 80%	Formal system approach	You are on the right track and are fully aware of the documentation that is needed for QMS and the steps involved in implementing QMS, including its review by Top Management. If your score is close to 40, then your documentation work is complete and you have followed proper steps of implementing QMS. Furthermore the Top Management would have also reviewed the results of implementation and found the system to be suitable and effective.
41 to 50	81 to 100%	Improvement approach	You are able to maintain all documents and records and also make improvements in the documentation and implementation, wherever possible.

Overall Assessment

Add the total score of all the four Parts (1 to 4) and check the overall assessment

Score	Percentage	Maturity level	Assessment
0 to 50	0 to 20%	Lack of awareness	You do not believe that you need a formal QMS.
51 to 100	21% to 40%	No formal approach	You are aware of the usefulness of QMS but have not been able to put a system in place. This requires first to decide the purpose of setting up a QMS, followed with designing and documenting the system and then operating and controlling the processes including taking corrective actions wherever found necessary.
101 to 200	41% to 80%	Formal system approach	You are on the right track and, if your total score is close to 200, it means that you have a fully functional QMS which is documented and implemented and its effectiveness and suitability is being periodically reviewed. Furthermore the system should be helping you to achieve improved customer satisfaction resulting in improvement in business results.
201 to 250	81 to 100%	Improvement approach	You are finding opportunities for improvement of your QMS and have also carried out some improvements based upon the analysis of data generated from the operation of QMS. If you are planning to obtain a third-party certification /registration of your QMS then you are ready for making an application for the same.

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ISO 9004:2009	Managing for the sustained success of an organization -- A quality management approach
ISO 19011:2011	Guidelines for auditing management systems
ISO 10001:2007	Quality management – Customer satisfaction – Guidelines for codes of conducts of organizations
ISO 10002: 2004	Quality management – Customer satisfaction – Guidelines for complaints handling in organizations
ISO 10003:2007	Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations
ISO/TS 10004:2010	Quality management -- Customer satisfaction -- Guidelines for monitoring and measuring
ISO 10005:2005	Quality management systems -- Guidelines for quality plans
ISO 10006:2003	Quality management systems -- Guidelines for quality management in projects
ISO 10007:2003	Quality management systems -- Guidelines for configuration management
ISO 10012: 2003	Measurement management systems -- Requirements for measurement processes and measuring equipment
ISO/TR 10013:2001	Guidelines for quality management system documentation
ISO 10014:2006	Quality management -- Guidelines for realizing financial and economic benefits
ISO 10015:1999	Quality management -- Guidelines for training
ISO/TR 10017:2003	Guidance on statistical techniques for ISO 9001:2000
ISO 10019:2005	Guidelines for the selection of quality management system consultants and use of their services
ISO/DIS 10018	Quality management −Guidelines on people involvement and competencies
ISO/IEC 90003:2004	Software Engineering − Guidelines for application of ISO 9001:2000 to computer software

International Organization for Standardizations (ISO), standards are obtainable from ISO or ISO members (list at www.iso.org).

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  This handbook gives guidance to small organizations on developing and implementing a quality management system based upon ISO 9001:2008. It offers some practical advice on different options should you wish to introduce a quality management system into your organization or update an existing one.

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- Survey of ISO 9000 certificates issued as on December 2009. http://www.iso.org/iso/survey2009.pdf

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- ISO Management Systems magazine database http://www.iso.org/iso/iso-management-systems. *The electronic editions from 2001 to 2009 of the ISO magazine 'ISO Management Systems' are available for consultation and downloading free of charge from the 'News and Media' section of the ISO website. They cover news, issues and developments related to ISO's management standards and their implementation around the world.*

- Selection and use of the ISO 9000 family of standards. http://www.iso.org/iso/iso_9000_selection_and_use-2009.pdf. *The brochure provides an overview of the standards in the ISO 9000 family and demonstrates how, collectively, they form a basis for continual improvement and business excellence. In addition to giving examples of the experience of users of the standards, it has sections on the following topics: description of the ISO 9000 core series standards; step-by-step process for implementing a quality management system; maintaining benefits and continual improvement; future of the ISO 9000 family*

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