1. SCOPE

The international standard provided guidelines beyond the requirements given in ISO 9001 in order to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization anticipate future demands. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization. This standard is driven by the quality and knowledge management principles.

This international standard is applicable to the processes of the organization. The focus of this international standard is the achievement of ongoing improvement, measured through the satisfaction customers, and other interested parties and knowledge management in organizations.

This international standard consists of guidance and recommendations and is not intended for certification regulatory or contractual use, or as a guide to the implementation of ISO 9001.

2. NORMATIVE REFERENCE

The following document constitutes the provisions of this international standard. For dated references, subsequent amendments to, or
revisions of, any of these publications don’t apply. However, parties to agreements based on this international standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid international standards.

3. **TERMS AND DEFINITION**

For the purpose of this international standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9004 to describe the supply-chain, have been changed to reflect the vocabulary currently used:

Supplier → organization → customer (interested parties)

Throughout the text of this international standard, wherever the term “product occurs, that also mean, “service”.
4. KNOWLEDGE MANAGEMENT BASED QUALITY SYSTEMS

4.1 Managing Systems and Processes

Leading and operating an organization successfully require managing it in a systematic and visible manner. Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organization’s performance by considering the needs of interested parties. Managing an organization includes quality management, knowledge management among other management disciplines.

Top management should establish a customer-oriented organization

a) By defining systems and processes that can be clearly understood, managed and improved in effectiveness as well as efficiency.

b) By ensuring effective and efficient operation and control of processes and measures and data used to determine satisfactory performance of the organization.

c) By optimum utilization of knowledge within and outside the organization.

d) By establishing the knowledge management framework and its components.
Examples of activities a customer-oriented organization include

- Defining and promoting processes that lead to improved organizational performance
- Acquiring and using process data and information on continuing basis
- Directing progress towards continual improvement
- Using suitable methods to evaluate process improvement, such as self-assessments and management review
- *Using intranet and internet to integrate islands of information and knowledge within and outside the organization*
- *Acquiring new knowledge assets, rather than just tapping the available information.*

### 4.2 Documentation

Knowledge Managed ISO 9001:2000 based Quality System-requirements

4 Knowledge Management based Quality System

4.1 General requirements

The organization shall establish, document, implement and maintain a *knowledge management based quality system* and continually improve its effectiveness in accordance with the requirements of this international standard.

The organization shall

a) Identify the processes needed for the quality management system and their application throughout the organization as *knowledge management stipulations.*

b) Determine the sequence and interaction of these processes.

c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.

d) Ensure the availability of resources and information necessary to
support the operation and monitoring of these processes.

e) Monitor, measure and analyze these processes.

f) Implement actions necessary to achieve planned results and continual improvement of these processes.

g) Identify key knowledge assets (tacit and explicit) of an organization.

h) With the help of CKO, find, select, organize, disseminate and transfer important knowledge and expertise necessary for various activities.

Management should define the documentation, including the relevant records, needed to establish, implement and maintain the quality management system and to support an effective and efficient operation of the organization’s processes and knowledge sharing.

The nature and extent of the documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectation of customers and other interested parties and should be appropriate to the organization. Documentation may be in any form or medium suitable for the needs of the organization.

In order to provide documentation to satisfy the needs and expectations of interested parties’ management should consider:

- Contractual requirements from the customer and other parties
- Acceptance of international, national, regional and industry sector standards
- Relevant statutory and regulatory requirements
- Decision by the organization
- Sources of external information relevant for the development of the organization competencies
• Information about the needs and expectations of relevant parties
• *Codification of relevant knowledge*
• *Continual flow of knowledge between the interested parties.*

The generation, use and control of documentation should be evaluated with respect to the effectiveness and efficiency of the organization against criteria such as,

• Functionality (such as speed and functioning)
• User friendliness
• Resources needed
• Policies and objectives
• Current and future requirements related to managing knowledge
• Benchmarking of documentation systems
• Interfaces used by organizations customers, suppliers and other interested parties.

Access to documentation should ensure for people in the organization and to other interested parties, based on the organization’s communications policy.

---

Knowledge Managed ISO 9001:2000 based Quality System-requirements
4.2 Documentation requirements
4.2.1 General

The *knowledge management based quality system* documentation shall include

a) A Documented statements of a *knowledge management based* quality policy and quality objectives.

b) A *knowledge management based* quality manual.

c) Documented procedures required by this international standard.

d) Documents needed by the organization to ensure the effective planning operation and control of its processes.
e) Records required by this international standard.

f) Documenting and accessing the knowledge.

g) Provisions to convert tacit knowledge to explicit knowledge.

h) Documents needed by the organization to ensure effective flow of knowledge.

Note: 1 Where the term “documented procedure” appears within this international standard, the means that the procedure is established, documented, implemented and maintained.

Note: 2 The extent of the quality management system documentation can differ from one organization to another due to

a) The size the organization and type of activities.

b) The complexity of processes and their interactions.

c) The competence of personnel.

d) Extent of computerization of activities of the organization.

e) Provisions to utilize information technology to share knowledge.

Note: 3 The documentation can be in any form or type of medium.

4.2.2 Knowledge Management based Quality manual

The organization shall establish and maintain a knowledge management based quality manual that includes

a) The scope of the quality management system, including details of the justification for any exclusion.

b) The documented procedures established for the quality management system, or reference to them.

c) A description of the interaction between the processes of the quality management system.

d) The link between quality management and knowledge management.

e) The knowledge management guidelines and procedures.
Knowledge Managed ISO 9001:2000 based Quality System-requirements

4.2.3 Control of documents

Documents required by the knowledge management based quality system shall be controlled. Records are special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procure shall be established to define the controls needed

a) To approve documents for adequacy prior to issue.

b) To review and update as necessary an e-approve documents.

c) To ensure that changes and the current revision status of documents are identified.

d) To ensure that relevant versions of applicable documents are available at points of use.

e) To ensure that documents remain legible and readily identifiable.

f) To ensure that documents of external origin are identified and their distribution controlled.

g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the knowledge management based quality system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.3 Use of Knowledge Management Based Quality Principles

To lead and operate an organization successfully, it is necessary to manage it in a systematic and visible manner. The guidance to management offered in this international standard is based on knowledge management based quality principles. These principles have been developed for use by top
management. Knowledge management based quality principles are integrated in the contents of this international standard and are listed below:

a) Customer focus
Organization depends on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

b) Leadership
Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization’s objectives.

c) Involvement of people
People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization’s benefit.

d) Process approach
A desired result is achieved more efficiently when activities and related resources are managed as a process.

e) System approach to management
Identifying understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its objectives.

f) Continual improvement
Continual improvement of the organization’s overall performance should be a permanent objective of the organization.
g) Factual approach to decision making
Effective decisions are based on the analysis of data and information.

h) Mutual beneficial supplier relationships
An organization and its suppliers are independent and mutually beneficial relationship enhances the ability of both to create value.

i) Align knowledge management and business strategy
Articulate a link between knowledge management and business strategy to analyze knowledge gaps and identify how knowledge management can fill these gaps, do a cost-benefit analyses to prioritize filling such gaps.

j) Knowledge sharing
It is fundamental to management processes surrounding knowledge management. There must be culture in which people are given recognition for knowledge sharing.

Successful use of the knowledge management and quality management principles by an organization will result in benefits to interested parties, such as improved monetary returns, creation of value and increased stability.
APPENDIX 3

KNOWLEDGE MANAGED
ISO 9001:2000 BASED QUALITY SYSTEM

5 MANAGEMENT RESPONSIBILITY
5.1 General Guidance
5.1.1 Introduction

Leadership, commitment, *knowledge assets* identification and the active involvement of the top management are essential for developing and maintaining an effective and efficient *knowledge management based quality system* to achieve benefits for interested parties. To achieve these benefits, it is necessary to establish, sustain and increase customer satisfaction. Top management should consider actions such as,

- Establishing a vision, policies and strategic objectives consistent with purpose of the organization
- Leading the organization by example, in order to develop trust within people
- Communicating organizational direction and values regarding quality and the quality management system
- Participating the improvement projects, searching for new methods, solutions and products
- Obtaining feed back directly on the effectiveness and efficiency of the quality management system
- Identifying the product realization processes that provide added value to the organization
• Identifying the product realization processes that provide added value to the organization
• Identifying the support processes that influence the effectiveness and efficiency of the realization processes
• Creating an environment that encourages the involvement and development of people
• Provision of the structure and resources that necessary to support the organization’s strategic plans
• *Establishing Internet and Intranet supported collaborative platform to create a knowledge management portal*
• *Creating an environment that encourages knowledge creation and sharing*
• *Applying and demonstrating the knowledge management practices*
• *Trying knowledge management initiation to the knowledge vision.*

Top management should also define methods for measurement of the organization’s performance in order to determine whether planned objectives have been achieved and develop criteria to measure the tangible benefits of Knowledge Management model.

• Financial measurement
• Measurement of process performance throughout the organization
• External measurement, such as bench marking an third party evaluation
• Assessment of the satisfaction of customers, people in organization and other interested parties
• Measurement of there success factors identified by management
• *Assessment of knowledge gained by the interested parties.*

Information derived from such measurements and assessments should also be considered as input to top management review in order to ensure that continual improvement of the quality management system is the driver for performance improvement of the organization.

5.1.2 **Issues to be considered**

When developing, implementing and managing the organization’s *knowledge management based quality system*, management should consider the knowledge and quality management principles outlined in 4.3.

On the basis of these principles, top management should demonstrate leadership in, and commitment to, the following activities:

• Understanding current and future customer needs and expectations, in addition to requirements
• Promoting policies and objectives to increase awareness, motivation and involvement of people in the organization
• Establishing continual improvement as an objective for processes of the organization
• Establishing continual improvement as an objective for processes of the organization
• Planning for the future of the organization and managing exchange
• Setting and communicating a framework for achieving the satisfaction of interested parties
• Integrating existing intranets, extranets, and groupware into knowledge management system
• Establishing continuous accumulation and dissemination of knowledge
• Identify key knowledge asset that will improve the performance of an organization.

In addition to small-step or ongoing continual improvement, top management should also consider break through changes to processes as away to improve the organization’s performance. During such changes, management should take steps to ensure that the resources and communication needed to maintain the functions of the knowledge management based quality system are provided.

Top management should identify the organization’s product realization processes, as these are directly related to the successes of the organization. Top management should also identify those support processes that affect either the effectiveness and efficiency of the realization processes or the needs and expectations of interested parties.

Management should ensure that processes operate as an effective and efficient network. Management should analyze and optimize the interaction of processes, including both realization processes and support processes.
Consideration should be given to:

- Ensuring that the sequence and interaction of processes are designed to achieve the desired results effectively and efficiently
- Ensuring process inputs, activities and outputs are clearly defined and controlled
- Monitoring inputs and outputs to verify that individual processes are linked and operate effectively and efficiently
- Identifying and managing risks, and exploiting performance improvement opportunities
- Conducting data analysis to facilitate continual improvement of processes
- Identifying process owners and giving them full responsibility and authority
- Managing each process to achieve the process objectives
- The needs and expectations of interested parties
- *Creating profiling mechanisms for knowledge delivery through problem solving techniques*
- *Identifying knowledge experts and share their knowledge with knowledge seekers*
- *Identifying and managing the knowledge assets to achieve the knowledge management objectives.*
a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.

b) Establishing the quality policy.

c) Ensuring that quality objectives are established.

d) Conducting management reviews.

e) Ensuring the availability of resources.

f) *Management commitment to improve knowledge of people by proper training and knowledge sharing between the employees.*

g) Designing the knowledge management team.

5.2 Needs and Expectations of Interested Parties

5.2.1 General

Every organization has interested parties, each party having needs and expectations. Interested parties of the organization include:

- Customer and end-users
- People in the organization
- Owners/investors (such as share holders, individuals or groups, including the public sector, that have a specific interest in the organization)
- Suppliers and partners
- Society in terms of the community and the public affected by the organization or its products
- *Knowledge users and seekers.*

5.2.2 Needs and Expectation

The success of the organization depends on understanding and satisfying the current and future needs and expectations of present and potential customers and end-users, as well as understanding and considering
those of other interested parties. In order to understand and meet the needs and expectations of interested parties, an organization should

- Identify its interested parties and maintain a balanced response to their needs and expectations
- Translate identified needs and expectations into requirements
- Communicate the requirements throughout the organization
- Focus on process improvement to ensure value for identified interested parties
- **Leveraging the knowledge assets of an organization**
- **Focus on knowledge management to ensure better services and processes**
- **Identifying the implemented tools and existing gaps in organization technology Infrastructure.**

To satisfy customer and end-user needs and expectations, the management of an organization should

- Understand the needs and expectations of its customers, including those of potential customers
- Determine key product characteristics for its customers and end users
- Identify and assess competition in its market
- Identify market opportunities, weaknesses and future competitive advantage
- **Clear definition of roles and responsibilities of the knowledge management workers.**
Examples of customer and end-user needs and expectations, as related to the organization’s products include:

- Conformity
- Dependability
- Availability
- Delivery
- Post realization activities
- Price and life-cycle costs
- Product safety
- Product reliability
- Environmental impact
- Product quality and service.

The organization should identify its people’s needs and expectations for recognition, work satisfaction, and personal development. Such attention helps to ensure that the involvement and motivation of people are strong as possible.

The organization should define financial and other results that satisfy the needs and expectations of owners and investors.

Management should consider the potential benefits of establishing partnerships with suppliers to the organization, in order to create value for both parties. A partnership should be based on a joint strategy, sharing knowledge as well as gains and losses.
When establishing partnerships, an organization should

- Identify key suppliers, and other organizations, as potential partners
- Jointly establish a clear understanding of customers needs and expectations
- Jointly establishing a clear understanding of partner’s needs and expectations
- Set goals to secure opportunities for continuing partnerships in considering its relationships with society, the organization should
- Demonstrate responsibility for health safety
- Consider environmental impact, including conservation of energy and natural resources, Identity applicable statutory and regulatory requirements
- Identify the current and potential impacts on society in general and the local community in particular, of its products, processes and activities.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

5.2 Customer focus
Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. The management utilizes the knowledge of the customers for the improving the total quality of the product.
5.2.3 Statutory and Regulatory Requirements

Management should ensure that the organization has knowledge of the statutory and regulatory requirements that apply to its products, processes and activities and should include such requirements as part of the knowledge management based quality system.

Consideration should also be given to:

- The promotion of ethical, effective and efficient compliance with current and prospective requirements
- The benefits of interested parties from exceeding compliance
- The role of the organization in the protection of community interests.

5.3 Knowledge Management based Quality Policy

The management should use the knowledge management based quality policy as a means of leading the organization toward improvements of its performance.

An organization’s knowledge management based quality policy should be an equal and consistent part of the organization’s overall policies and strategy.

In establishing the knowledge management based quality policy, top management should consider.
• The level and type of future improvement needed for the organization to be successful
• The expected or the desired degree of customer satisfaction
• The development of people in the organization
• The needs and expectations of interested parties
• The resources needed to go beyond ISO 9001 requirements
• The potential contributions of supplier and partners
• **The importance of knowledge management in improving quality**
• **The role of knowledge management system in the organization**
• The quality policy can be used for improvement provided that
• It is consistent with top management's vision and strategy for the organization future
• Its permits quality objectives to be understood and pursued through the organization
• It demonstrates top management commitment to quality and the provision of adequate resource for achievement of objectives
• It aids in promoting commitment to quality throughout the organization, with clear leadership by top management
• It includes continual improvement as related to satisfaction of the needs and expectation of customers and other interested parties
• It is effectively formulated and efficiently communicated.

As with other business policies, the **knowledge management based** quality policy should be periodically reviewed.
Knowledge Managed ISO 9001:2000 based Quality System—requirements

5.3 **Knowledge Management based** Quality policy

Top management shall ensure that **knowledge management based** quality policy

a) Is appropriate to the purpose of the organization.

b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system.

c) Provides a framework for establishing and reviewing quality objectives.

d) Is communicated and understood within the organization.

e) Is reviewed for continuing suitability.

f) **Knowledge growth in the organization.**

---

5.4 **PLANNING**

5.4.1 **Knowledge Management based** Quality objectives

The organization’s strategic planning and the quality provide a framework for setting of quality objectives. Top management should establish these objectives leading to improvement of the organizations performance. The objectives should be capable of being measured in order to facilitate an effective and efficient review by management. When establishing these objectives, management should also consider

- Current and future needs of the organization and the market served
- Relevant findings from management review
- Current product and process performance
- Level of satisfaction of interested parties
- Self-assessment results
- Benchmarking, competitor analysis, opportunities for improvement
- Resources needed to meet the objectives
- *The role of Information Technology in improving the quality of product*
- *Central objective and scope of knowledge management.*

The quality objective should be communicated in such a way that people in the organization can contribute to their achievement. Responsibility for deployment of quality objectives should be defined. Objectives should be systematically reviewed and revise as necessary.

<table>
<thead>
<tr>
<th>Knowledge Managed ISO 9001:2000 based Quality System-requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.4 Planning</td>
</tr>
<tr>
<td>Top management shall ensure that quality objectives, including</td>
</tr>
<tr>
<td>those needed to meet requirement for product, are established</td>
</tr>
<tr>
<td>at relevant functions and levels within the organization. The</td>
</tr>
<tr>
<td>quality objectives shall be measurable and consistent with the</td>
</tr>
<tr>
<td>quality policy.</td>
</tr>
</tbody>
</table>

5.4.2 **Knowledge Management based Quality Planning**

Management should take responsibility for the quality planning of the organization. This planning should focus on defining the processes needed to meet effectively and efficiently the organization *knowledge management based* quality objectives and requirements consistent with strategy of the organization.

Inputs for effective and efficient planning include:

- Strategic of the organization
• Defined organization objectives
• Defined needs and expectations of the customers and other interested parties
• Evaluation of statutory and regulatory requirements
• Evaluation of performance data of the product
• Lessons learned from previous experience
• Indicated opportunities for improvement
• Related risk assessment and mitigation data
• **Measurement and evaluation of knowledge management benefits**
• **Sources of knowledge constructions**
• **Auditing the existing knowledge of an organization**
• **Identifying organizations knowledge-spots.**

Outputs of quality planning for the organization should define the product realization and support processes needed in terms such as,

• Skills and knowledge needed by the organization
• Responsibility and authority for implementation of processes improvement plans
• Resources needed such as financial and infrastructure
• Metrics for evaluating achievements of the organizations performance improvements
• Needs for improvement including methods and tools
• Needs for documentation, including records and easy accessibility to the appropriate personnel.

Management should systematically review the outputs to ensure the effectiveness and efficiency of the processes of the organization.
5.4.2 Knowledge management based quality planning

Top management shall ensure that

a) The planning of Quality management system is carried out in order to meet the requirements given in 4.1 as well the quality objectives.

b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

c) The top management should be enthusiastic to integrate the quality management with knowledge management.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management should define and then communicate the responsibility and authority in order to implement and maintain an effective and efficient knowledge management based quality system.

People throughout the organization should be given responsibilities and authority to enable them to contribute to the achievement of the quality objectives and to establish their involvement, motivation and commitment.
5.5.2 Management Representative

A Management representative should be appointed and given authority by top management to manage, monitor, evaluate and coordinate the knowledge management based quality system. This appointment is to enhance effective and efficient operation and improvement of the knowledge management based quality system. The representative should report to top management and communicate with customer and other interested parties on matters pertaining to knowledge management based quality system. Management has to appoint a Chief Knowledge Officer to implement knowledge management in the organization.

Knowledge Managed ISO 9001:2000 based Quality System-requirements
5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) Ensuring that processes needed for quality system are established, implemented and maintained.

b) Reporting to top management on the performance of quality management system and any need for improvement.

c) Ensuring the promotion of awareness of customer requirement through out the organization.

d) Making aware the people of organization about new knowledge portals.

NOTE: The responsibility of a top management representative can include liaison with external parties on matters relating to knowledge management based quality system.
5.5.3 Internal Communication

The management of the organization should define and implement an effective and efficient process for communicating the quality policy, requirements, objectives and accomplishments. Providing such information can aid in the organization’s performance improvement and directly involves its people in the achievement of knowledge management based quality objectives. Management should actively encourage feedback and communication from people in the organization as means of involving them.

Activities for communicating include, for example,

- Management-led communication in work areas
- Team briefing and other meetings, such as recognition for achievement
- Notice-boards, in house journals/magazines
- Audio-visual electronic media, such as email and websites
- Employee survey and suggestion schemes
- Using intranet, knowledge portal
- Conducting frequent videoconferences
- Conducting seminars about recent trends.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

5.5.3 Internal communication

Top management shall ensure that appropriate communication channels are established within the organization that communication takes place regarding the effectiveness of the knowledge management based quality system. The management has to provide electronic and other communicating techniques in the organization.
Top management should develop the management review activity beyond verification of the effectiveness and efficiency of the *knowledge management based quality system* into a process that extends to the whole organization, and which also evaluates the efficiency of the system. Management review should be platform for the exchange of new ideas, with open discussion and evaluation of the inputs being simulates by leadership of top management.

To add value to the organization from management review, top management should control the performance of realization and support process by systematic review based on quality management principles. The frequency of review should be determined by the needs of the organization. Inputs to the review process should result in outputs that extend beyond the effectiveness and efficiency of the *knowledge management based quality system*. Output from review should provide data for use in planning for performance improvement of the organization.

*Knowledge about the knowledge assets of an organization is critical to the planning of a knowledge management system. Knowledge assets are rich source of information to assess the performance of the organization.*

<table>
<thead>
<tr>
<th>Knowledge Managed ISO 9001:2000 based Quality System-requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.6 Management review</td>
</tr>
<tr>
<td>5.6.1 General</td>
</tr>
</tbody>
</table>

Top management shall review the organization’s *knowledge management based quality system*, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to quality management system, including the quality and quality objectives. *Knowledge audit is performed frequently (at least one in every 6 months).* *The audited knowledge asset is codified in the form of documents.* Records from management review shall be maintained.
5.6.2 Review Input

Inputs to evaluate efficiency as well as effectiveness of the *knowledge management based quality system* should consider the customer and other related parties and should include:

- Status and result of quality objectives and improvement activities
- Status of management review action items
- Results of audits and self assessment of the organization
- Feedback on the satisfaction of interested parties, perhaps even to the point
- Market related factors such as technology, research and development
- Results from bench marking
- Performance of suppliers
- New opportunities for improvement
- Control of process and product nonconformities
- Market place evaluation and strategies
- Status of strategic partnership activities
- Financial effects of quality related activities
- Other factor which may impact the organization, such as financial, social or environmental conditions, and relevant statutory and regulatory changes

*Identify company’s knowledge spots and direction in which it must focus.*
5.6.3 Review Output

By extending management review beyond verification of the knowledge management based quality system. Top management can use the output of management review as inputs to improvement processes. Top management can use this review process as a powerful tool in the identification of opportunities for performance improvement of the organization. The schedule of review should facilitate the timely provision of data in the context of strategic planning for the organization. Selected output should be communicated to demonstrate to the people in the organization how the management review process leads to new objectives that will benefit the organization.

Additional output to enhance efficiency include, for example,

- Performance objectives for product and processes
- Performance improvement objectives for the organization
- Appraisal of the suitability of the organization structure and resources
- Strategies and initiatives for marketing, products, and satisfaction of customers and other interested parties
- Loss prevention and mitigation plans for identified risks
- Information for strategic planning for future needs of the organization
- Reviewing the outputs of Knowledge Management by using Results-Driven-Incremental (RDI) methodology.

Records should be sufficient to provide for traceability and facilitate evaluation of the management review process itself, in order to ensure its continued effectiveness and added value to the organization.

<table>
<thead>
<tr>
<th>Knowledge Managed ISO 9001:2000 based Quality System-requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.6.3 Review output</td>
</tr>
<tr>
<td>The output from management review shall include any decision and action’s related to</td>
</tr>
<tr>
<td>a) Improvement of the effectiveness of the knowledge management based quality system and its processes.</td>
</tr>
<tr>
<td>b) Improvement of product related to customer requirements.</td>
</tr>
<tr>
<td>c) Resource needs.</td>
</tr>
<tr>
<td>d) Exploiting knowledge assets.</td>
</tr>
<tr>
<td>e) Creation of effective knowledge management team.</td>
</tr>
</tbody>
</table>
APPENDIX 4

KNOWLEDGE MANAGED
ISO 9001:2000 BASED QUALITY SYSTEM

6 RESOURCE MANAGEMENT
6.1 General Guidance
6.1.1 Introduction

Top management should ensure that the resources essential to the implementation strategy and the achievement of the organization’s objective are identified and made available. This should include resource for operation and improvement of the knowledge management based quality system, and the satisfaction of customer and other interested parties. Resources may be people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources.

6.1.2 Issues to be considered

Consideration should be given to resources to improve the performance of the organization, such as,

- Effective, efficient and timely provision of resources in relation to opportunities
- Tangible resources such as improve realization and support facilities
- Intangible resources such as intellectual property, knowledge assets
- Resource and mechanism to encourage innovative continual improvement
- Organization structures, including project and matrix management needs
- Information management and technology
- Enhancement of competence via focused training, education and learning
- Development of leadership skills and profiles for the future manager of the organization
- Use of natural resources and the impact of resources of the environment
- Planning for future resources needs.

Knowledge Managed ISO 9001:2000 based Quality System-requirements
6. Resource Management
6.1 Provision of Resources
The organization shall determine and provide the resources needed
  a) To implement and maintain the knowledge management based quality system and continually improves its effectiveness.
  b) To enhance customer satisfaction by meeting customer requirements.
  c) To implement knowledge management in the organization.

6.2 PEOPLE
6.2.1 Involvement of People

Management should improve both the effectiveness and efficiency of the organization, including the knowledge management based quality
system, through the involvement, knowledge sharing and support people. As an aid to achieving its performance improvement objectives, the organization should encourage the involvement of its people.

- By providing on going training and career planning
- By defining their responsibilities and authorities
- By establishing individual and team objective setting and decision making
- By recognition and rewarding
- By facilitating open, two way communication of information
- By continual reviewing the needs of its people
- By creating condition to encourage innovation
- By ensuring effective team work
- By communicating suggestion and opinion
- By using measurements of it’s people satisfaction
- By investigating the reason why people join and leave organization

- **By proper knowledge sharing tools to empower the knowledge of people**
- **Identifying tacit knowledge**
- **Facilitating knowledge flow among people.**

<table>
<thead>
<tr>
<th>Knowledge Managed ISO 9001:2000 based Quality System-requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.2 Human Resources</td>
</tr>
<tr>
<td>6.2.1 General</td>
</tr>
<tr>
<td>Personal performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, knowledge and experience.</td>
</tr>
</tbody>
</table>
6.2.2 Competence Awareness and Training

6.2.2.1 Competence

Management should ensure that the necessary competence is available for the effective and efficient operation of the organization. Management should consider analysis of both the present and expected competence needs as compared to the competence already existing in the organization.

Consideration of the needs for competence include source such as,

- Future demand related to strategic and operational plans and objectives
- Anticipated management and work force succession model
- Changes to the organization’s processes, tool and equipment
- Evaluation of competence of individual people to perform defined activities
- Statuary and regulatory requirements, and standards, affecting the organization and it interested parties
- *Anticipating future trends of product using knowledge management techniques*
- *Estimating the knowledge assets of the competitor.*

6.2.2.2 Awareness and training

Planning for education and training needs should take account of changes caused by the nature of the organization’s processes, the stages of development of people and culture of the organization.
The objective is to provide people with knowledge and skills, which, together with experience, improve their competence.

Education and training should emphasize the importance of meeting requirements and the needs and expectation of the customer and other interested parties. It should also include awareness of consequence to the organization and its people falling to meet the requirements.

To support the achievement of the organization’s objectives and the development of its people, planning for education and training should consider

- Experience of people
- Tacit and explicit knowledge of individuals
- Leadership and management skills
- Planning and improvement tools
- Team building
- Problem solving
- Communication skills
- Culture and social behavior
- Knowledge of markets and the needs and expectation of customers and other interested parties
- Creativity and innovation
- To facilitate involvement of people, education and training also include
- The vision for the future of the organization
- The organization’s policies and objectives
- Organizational change and development
- The initiation and implementation of improvement processes
• Benefits from creativity and innovation
• The organization’s impact on society
• The benefits of knowledge sharing
• Introductory program’s for new people
• Periodic refresher programs for people already trained
• Training plan should include objectives, programs and methods, resources needed
• Identification of necessary internal supports
• Evaluation in terms of enhanced competence of people
• Measurement of the effectiveness and the impact of the organization

• Knowledge management barriers
• Plans to overcome knowledge management barriers
• The education and training provided should be evaluated in terms of expectation and impact on the effectiveness and efficiency of the organization as means of improving future training plans.

<table>
<thead>
<tr>
<th>Knowledge Managed ISO 9001:2000 based Quality System - requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.2.2 Competence, awareness and training</strong></td>
</tr>
<tr>
<td>The organization shall</td>
</tr>
<tr>
<td>a) Determine the necessary competence for personal performing work affecting product quality.</td>
</tr>
<tr>
<td>b) Providing training or take other actions to these needs.</td>
</tr>
<tr>
<td>c) Evaluate the effectiveness of action taken.</td>
</tr>
<tr>
<td>d) Ensure that its personal are aware of the relevance and importance of their activities and how they contribute to the achievement of the knowledge management based quality objectives.</td>
</tr>
<tr>
<td>e) Maintain appropriate records of education training skills and experience.</td>
</tr>
</tbody>
</table>
6.3 Infrastructure

Management should define the infrastructure necessary for realization of products while considering the needs and expectation of interested parties. The infrastructure includes resources such as plant, workspace, tools and equipment, support services, information and communication technology, and transport facilities.

The process to define the infrastructure necessary for achieving effective and efficient product realization should include the following:

a) Provision of infrastructure, defined in terms such as objectives, function, performance, availability, cost, safety, security and renewal.

b) Development and implementation of maintenance methods to ensure that the infrastructure continues to meet the organization’s needs these methods should consider the type and frequency of maintenance and verification of operation of each infrastructure element, based on its critical usage.

c) Evaluation of the infrastructure against the needs and expectation of interested parties.

d) Consideration of environmental issues associated with infrastructure, such as conservation, pollution, waste and recycling.

e) Provision of infrastructures required for knowledge sharing.

Natural phenomenon that cannot be controlled can impact the infrastructure. The plan for the infrastructure should consider the identification and mitigation of associated risks and should include strategies to protect the interest of interested parties.
6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirement. Infrastructure include, as applicable

a) Buildings, workspace and associated utilities.

b) Process.

c) Equipment (both hardware and software).

d) Supporting services (such as transport or communication).

e) The infrastructure needed to implement knowledge management.

6.4 Work Environment

Management should ensure that the work environment has a positive influence on motivation, satisfaction and performance of in order to enhance the performance of the organization. Creation of suitable work environment, as a combination of human and physical factors, should include consideration of:

- Creative work methods and opportunities for greater involvement to realize the potential of people in the organization
- Safety rules and guidance, including the use of protective equipment
- Ergonomics
- Work place location
- Social interaction
- Facilities for the people in the organization
- Heat humidity, light, air flow
- Hygiene, cleanliness, noise, vibration and pollution
6.4 Work environment
The organization shall determine and manage the work environment needed to achieve conformity to product requirement. The organization shall establish the environment to implement and maintain knowledge management in the organization.

6.5 Information

Management should treat data a fundamental resource for conversation to information and the continual development of an organization’s knowledge, which is essentially for making factual decision and simulate innovation. In order to manage information, the organization should

- Identify its information needs
- Identify and access internal and external sources of information
- Convert information to knowledge set and meet its strategies and objectives
- Ensure appropriate security and confidentiality
- Evaluate the benefit derived from use of the information in order to improve managing information and knowledge
- Identifies sources of knowledge
- Identify types of knowledge whether it is available in the form of documents.
6.6 Supplier and Partnerships

Management should establish relationship with supplier and partners to promote and facilitate communication with the aim of mutually improving the effectiveness and efficiency of processes that create value. There are various opportunities for the organization to increase value through working with their supplier and partner such as,

- Optimizing the number of suppliers and partners
- Establishing two-way communicational appropriate levels in both organizations to facilitate the rapid solution of problems, and to avoid costly delays or disputes
- Co-operating with suppliers in validation of the capability of the processes
- Monitoring the ability of suppliers to deliver conforming products with the aim of eliminating redundant verification
- Encouraging suppliers to implement program for continual improvement of performance and to participate in other joint improvement initiatives
- Involving partners in identification of purchasing needs and joint strategy development
- Evaluating, recognizing and rewarding efforts and achievements by supplier and partners.

6.7 Natural Resources

Consideration should be given to the availability of natural resources that can influence the performance of the organization. While such resources are often out of the direct control of organization, they can have can
have significant positive or negative effects on its results. The organization should have plans, or contingency plans, to ensure the availability or replacement of these resources in order to prevent or minimize negative effects on the performance of the organization.

6.8 Financial Resources

Resource management should include activities for determining the needs for, and sources of, financial resources. The control of financial resources should include activities for comparing actual usage against plans and taking necessary action.

Management should plan, make available and control the financial resources necessary to implement and maintain an effective and efficient knowledge management based quality system and to achieve the organization’s objectives, management should also consider the development of innovative financial methods to support and encourage improvement of the organization’s performance. Develop budget managing resources allocation designing capital structure, managing cash flow and financial risks.

Improving the effectiveness and efficiency of the knowledge management based quality system can influence positively the financial results of the organization, for example,

a) Internally by reducing process and product failures, or waste material and time.

b) Externally, by reducing product failures, cost of compensation under guarantees and warranties, and cost of lost customers and market.
Reporting of such matters can also provide a means of determining ineffective or inefficient activities, and initiating suitable improvement actions.

The financial reporting of activities relates to the *knowledge management based quality system* and product conformity should be used in management reviews.
7 PRODUCT REALIZATION
7.1 General Guidance
7.1.1 Introduction

Top management ensures the effective and efficient operation of realization and support processes network so that the organization has the capability of satisfying its interested parties. While realization processes results in product that add value to the organization, support processes are also necessary to the organization an add value indirectly.

The interrelation of processes can be complex, resulting in processes networks, to ensure the effective and efficient operation of the organization. Management should recognize that the output of one process might become the input to one more other processes.

7.1.2 Issues to be considered

Understanding that a process can be represented as a sequence of activities aids management in defining the processes input. Once the inputs have been defined, the necessary activities, action and resources required for the processes can be determined, in order to achieve the desired outputs.

Process should be documented to the extent necessary to support effective and efficient operation. Documentation relate to processes should support
- Identifying and communicating the significant features of processes
- Training in the operation of processes
- Sharing knowledge and experience in team and work groups
- Measurement and audit of processes
- Analyze review and improvement of processes
- Convert information into knowledge.

7.1.3 Managing Processes

7.1.3.1 General

Management should identify processes needed to realize products to satisfy the requirements of customer and other related parties. To ensure product realization, consideration should be given to associated support processes as well as desired outputs, processes steps, activities, flows, control measures, training needs, equipment, methods, information, material and other resources.

An operation plan should be defined to manage the processes, including,

- Input and output requirements
- Activities within the processes
- Verification and validation of processes and products
- Analysis of processes using depended ability
- Identification, assessment and mitigation of risk
- Corrective and preventive action
- Opportunities and actions for processes improvement
- Control of changes to processes and product

Improve the usage level of knowledge portal for knowledge sharing.
7.1.3.2 Processes inputs, outputs and review

The processes approach ensures that the process input are defined and recorded in order to provide a basis for formulation of requirements to be used for verification and validation of outputs. Inputs can be internal or external to the organization.

Examples of inputs issues to be consider include,

- Competence of people
- Documentation
- Equipment capability and monitoring
- Health, safety and work environment.

The management of organization should undertake periodic review of process performance to ensure the process is consistent with the operating plan. Examples of topics for review include,

- Reliability and repeatability of process
- Identification and prevention of potential nonconformities
- Adequacy of design and development inputs and outputs
- Consistency of input and output with planned objectives
- Potential for improvement
- Unresolved issues.

Knowledge Managed ISO 9001:2000 based Quality System requirements
7 Product Realizations
7.1 Planning for product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of other processes of the knowledge management based quality system.
In planning product realization, the organization shall determine the following, as appropriate

a) Required verification, validation, monitoring, inspection, and test activities specific to product the product and criteria for product acceptance.

b) Records needed to provide evidence that the realization processes and resulting product meet the requirement.

c) **Knowledge management based** quality objective and requirement for the product.

d) The need to establish processes, documents, and provide resources specific to the product.

e) *The right approach to utilize knowledge management tools to get optimum product realization processes.*

### 7.1.3.3 Product and processes validation changes

Management should ensure that the validation of product demonstrate that they meet the needs and expectation of customer and other interested parties. Validation activities include modeling, simulation and trials, as well as reviews involving customers and other interested parties.

Issues to consider should include,

- **Knowledge management based** quality policy and objectives
- Capability or qualification of equipment
- Operating and condition of product
- Use or application of the product
- Disposal of the product
- Product life cycle
- Environmental impact of the product
• Impact of the natural resources including materials and energy.

Process validation should be carried out at appropriate intervals to ensure timely reaction to change impacting the process. Particular attention should be given to validation of processes.

• For high value and safety critical products
• Where deficiency in product will only be apparent in use
• Which cannot be repeated
• Where verification of product is not possible.

7.2 Processes Related Interested Parties

Management should ensure that the organization has defined mutually acceptable process for communicating effectively and efficiently with its customers and other interested parties. The organization should implement and maintain such processes to ensure adequate understanding of the needs and expectation of its interested parties, and for transition in to requirements for the organization. Theses processes should include identification and review of relevant information and should actively involve customers and other interested parties. Examples of relevant process information include:

• Requirement of customer and other interested parties
• Market research, including sector and end-user data
• Contract requirements
• Competitor analysis
• Benchmarking
- Process due statutory and regulatory requirements
- Knowledge managed quality management system is transparent.

Knowledge Managed ISO 9001:2000 based Quality System - requirements

<table>
<thead>
<tr>
<th>7.2 Customer-related processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2.1 Determination of requirement related to product</td>
</tr>
</tbody>
</table>

The organization shall determine

- a) Requirements specified by customers, including the requirements for delivery and post delivery activities.
- b) Requirements not stated by the customers but necessary for specified or intended use, where unknown.
- c) Statutory and regulatory requirements related to product.
- d) Any additional requirement determined by the organization.
- e) **Requirements specified by the Chief Knowledge Officer about product realization.**

<table>
<thead>
<tr>
<th>7.2.2 Review of requirements related to the product</th>
</tr>
</thead>
</table>

The organization shall review the requirements related to the product. This review shall be prior to the organisation’s commitment to supply a product to the customer (e.g. Submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) Product requirements are defined
- b) Contract or order requirements differing from those previously expressed are resolved
- c) The organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that
relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Note: In some situations, such as internal sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating customer in relation to

a) Product information.

b) Enquiries, contacts or order handling, including amendments.

c) Customer feedback, including customer complaints.

7.3 Design and Development

7.3.1 General Guidance

Top management should ensure that the organization has defined, implemented and maintained the necessary design and development processes to respond effectively and efficiently to the needs and expectation of its customer and other interested parties.

Management also has the responsibility to ensure that the steps are taken to identify and mitigate potential risk to the users of the product and processes of the organization. Risk assessment should be undertaken to assess the potential for, and the effect of possible failures of fault in product or processes. The result of the assessment should be used to define and implement preventive actions to mitigate the define risks. Examples of tools for risk assessment of design and development include:

- Design fault modes and effects analysis
- Fault tree analysis
- Reliability prediction
- Relationship diagrams
- Ranking technique
- Simulation technique

Knowledge Managed ISO 9001:2000 based Quality System-requirements

7.3 Design and development

The organization shall plan and control the design and development of product.

During the design and development planning the organization shall determine

a) The Design and Development stage.

b) The review verification and validation that is appropriate to each design and development stage.

c) The responsibilities and authorities for design and development.

7.3.2 Design and Development Input and Output

The organization should identify process inputs that affect the design and development of products and facilitate effective and efficient process performance in order to satisfy the needs and expectation of customers, and those of the interested parties. These external needs and expectation, coupled with those internal to the organization. Should be suitable for translation into input requirement for the design and development processes.

Examples are as follows:

a) External input such as
   - Customer and market place needs and expectation
- Needs and expectation of other interested parties
- Supplier contribution
- User input to achieve robust design and development
- Changes in relevant statutory and regulatory requirements
- International or national standards
- Industry codes of practice.

b) Internal input such as
- Policies and objectives
- Needs and expectation of people in the organization, including those receiving and output of the process
- Technological development
- Competence requirement for people performing design and development
- Feedback information from past experience
- Records and data on existing process and products
- Outputs from other processes.

c) Inputs that identify those characteristics of processes or products that are crucial to safe and proper functioning and maintenance such as
- Operation, installation and application
- Storage, handling and delivery
- Physical parameters and the environment
- Requirement for disposal of products.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

7.3.2 Design and development inputs

Input relating to product requirements shall be determined and records maintained. These shall include
a) Functional and performance requirements.

b) Applicable statutory and regulatory requirements.

c) Where applicable, information derived from previous similar designs.

d) Other requirements essential for design and development.

7.3.3 Design and Development Review

Top management should ensure that appropriate people are assigned to manage and conduct systematic reviews to determine that design and development objectives are achieved. These reviews may be conducted at selected points in the design and development process as well as at completion.

Examples of topics for such review include:

- Adequacy of input to perform the design and development tasks
- Progress of the planned design and development process
- Meeting verification and validation goals
- Evaluation of potential hazards
- Life cycle data on performance of product
- Control of changes and their effects during the design and development process
- Identification and correction of process
- Opportunities for design and development process improvement
- Potential impact of the product on the environment.
### 7.3.4 Design and development review

At suitable stages, systematic review of design and development shall be performed in accordance with planned arrangements:

a) To evaluate the ability of results design and development of meet requirements.

b) To identify any problems and process necessary actions.

### 7.3.5 Design and development validation

Design and Development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirement for specified application or intended use, when known. Wherever practical, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary action shall be maintained.

### 7.4 Purchasing

#### 7.4.1 Purchasing Process

Top management of the organization should ensure that the effective and efficient purchasing process are defined and implemented for the evaluation and control of purchased product, in order that purchased products satisfy the organization’s needs and requirements, as well as those of interested parties.

Use of electronic linkage with supplier should be considered in order to optimize communication of requirements.
To ensure the effective and efficient performance of the organization, management should ensure that the purchasing processes consider the following activities:

- Timely, effective and accurate identification of needs and purchased product specification
- Evaluation of the cost of purchased product, taking account of product, performance, price and delivery
- The organization need and criteria for verifying purchased products
- Unique supplier processes
- Consideration of contract administration, for both supplier and partner arrangements
- Warranty replacements for nonconforming purchased products
- Logistics requirements
- Product identification and traceability
- Preservation of product
- Documentation, including records
- Control of purchased product which deviates from requirements
- Access to supplier’s premises
- Product delivery, installation or application history
- Supplier development
- Identification and mitigation of risks associated with the purchased product.
7.4.2 Supplier Control Process

The organization shall establish effective and efficient process to identify potential sources for purchased materials, to develop existing supplier or partners, and to evaluate their ability to supply the required products in order to ensure the effectiveness and efficiency of overall purchasing processes.

Examples of inputs to supplier control process include:

- Evaluation or relevant experience
- Performance of supplier against competitors
- Review of purchased product quality, price, delivery performance and response to problem
- Audits of supplier management system and evaluation of their potential capability to provide the required products effectively and efficiently and within schedule
- Checking supplier references and available data on customer satisfaction.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

7.4 Purchasing

7.4.1 Purchasing processes

The organization shall ensure that purchased product confirm to specified purchase requirements. The type and extent of control applied to supplier and the purchased product shall be dependent upon effect of the purchased product on subsequent product realization or the final product.

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate
a) Requirements for approval of product, procedures, processes, and equipment.
b) Requirement for qualification of personnel.
c) **Knowledge management based quality** system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to the communication to the supplier.

7.4.3 Verification of purchase product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier’s premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

### 7.5 Product and Service Operations

#### 7.5.1 Operation and Realization

Top management should go beyond control of realization of the process in order to achieve both compliance with requirements and provide benefits to interested parties. This may be achieved through improving the effectiveness and efficiency of realization processes and associated support process, such as,

- Reducing waste
- Training of people
- Communicating and recording people
- Developing supplier capability
- Improving infrastructure
• Preventing problems
• Processing methods and process yield, and
• Methods of monitoring.

Knowledge Managed ISO 9001:2000 based Quality System-requirements
7.5  Production and service provision
7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled condition shall include, as applicable:

a) The availability of information that describes the characteristics of the product.

b) The availability of work instructions as necessary.

c) The use of suitable equipment.

d) The availability and use of measuring and monitoring devices.

e) The implementation of monitoring and measurement.

f) The implementation of release, delivery and post-delivery activities.

7.5.2 Validation of process for production and service provision

The organization shall validate any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product in use or the service has been delivered.

7.5.2 Identification and Traceability

The organization can establish a process for identification and traceability that goes beyond the requirements in order to collect data, which can be used for improvement.
The need for identification and traceability may arise from

- Status of product, including components parts
- Status and capability of processes
- Benchmarking performance data, such as product recall capability
- Relevant statutory and regulatory requirements
- Intended use of application
- Hazardous material
- Mitigation of identified risks.

Knowledge Managed ISO 9001:2000 based Quality System - requirements

7.5.3 Identification and traceability
Where appropriate, the organization shall identify the product by suitable means throughout product realization.
The organization shall identify the product status with respect to monitoring and measurement requirements.
Where traceability is a requirement, the organization shall control and record the unique identification of product.

7.5.3 Customer Property

The organization should identify responsibilities in relation to property and other assets owned by customer and other interested parties and under the control of the organization, in order to protect the value of property. Examples of such property are,

- Ingredients or components supplied for inclusion in a product
- Products supplied for repair, maintenance or upgrading
• Packing materials supplied directly by the customer
• Customer materials handled by service operation such as storage
• Service supplied on behalf of the customers, such as transport of customer property to third party
• Customer intellectual property including specification, drawings and propriety information.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization’s control or being used by organization. The organization shall identity, verity, protect and safeguard customer property provided for use or incorporation in to the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

7.5.4 Preservation of Product

Management should define and implement processes for handling, packaging, storage, preservation and delivery of product that prevent damage, deterioration or misuse during internal processing and final delivery of the product. Management should involve supplier and partners in defining and implementing efficient and effective and efficient processes to protect purchase material.

Management should consider the need for any special requirement arising from the nature of the product. Special requirements can be associated
with software, electronic media, hazardous material, and product requiring special people for service, installation or application, and product or materials that are unique or irreplaceable.

Management should identify resources needed to maintain the product throughout its life cycle to prevent damage, deterioration or misuse. The organization should communicate information to interested parties involved about the resources and method needed to preserve the intended use of the product throughout its life cycle.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shell includes identification, handling, packaging, storage and protection. Preservation shell also applies to the constituent of a product.

7.6 Control of Monitoring and Measuring Devices

Management should define and implement effective and efficient measuring and monitoring processes, including methods and devices for verification and validation of products and processes to ensure the satisfaction of customers and other interested parties. Theses processes include surveys, simulation, and other measurement and monitoring activities.

In order to provide confidence in data, the measuring and monitoring processes should confirmation that the devices are fit for use and are maintained to suitable accuracy and accepted standards, as well as a means of identifying the status of the devices.
The organization should consider means to eliminate potential errors from processes, such as “pool-proofing”, for verification of process outputs in order to minimize the need for control of measuring and monitoring devices, and to add value for interested parties.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary the ensure valid results, measuring equipment shall

a) Be adjusted or re-adjusted as necessary.

b) Be identified to enable a calibration status to be determined.

c) Be safeguarded from adjustment that would invalidate the measurement result.

d) Be protected from damage and deterioration during handling, maintenance and storage.

e) Be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standard; where no such standard exist, basis used for calibration or verification shall be recorded.
APPENDIX 6

KNOWLEDGE MANAGED
ISO 9001:2000 BASED QUALITY SYSTEM

8 MEASUREMENT ANALYSES AND IMPROVEMENT
8.1 General Guidance
8.1.1 Introduction

Measurement data are important for making fact-based decisions. Top management should ensure effective and efficient measurement, collection and validation of data to ensure the organization’s performance and the satisfaction of interested parties. This should include review of the validity and purpose of measurements and the intended use of data to ensure added value to the organization. Top management should provide the provision to transfer data in to information, which then transfers to knowledge, which is key asset of organization. To achieve this top management has to employee data analyst who sees after the issues related to data management.

Examples of performance of the organization’s process include,

- Measurement and evaluation of its products
- Capability processes
- Achievement of project objectives
- Satisfaction of customer and other interested parties
- Measuring effective utilization of information technology investments
- Measurement of intangible asset.

8.1.2 Issues to be considered

Measurement, analysis, improvement include the following consideration:
a) Measurement data should be converted to information knowledge to be of benefit to the organization.

b) Measurement of customer satisfaction should be considered as vital for evaluation of the organization performance.

c) Use of measurements, generating and communicating of the information obtained, is essential to the organization and should be the basis for performance improvement and the involvement of improved parties. Such information should be current, and purpose should be clearly defined.

d) Appropriate tools for communication of information resulting from the analysis of measurement should be implemented.

e) The effectiveness and efficiency of communicating with interested parties should be measured to determine whether the information is timely and clearly understood.

f) Where process and product performance criteria are met, it may still be beneficial to monitor and analyze performance data in order to understand better the nature of the characteristics understudy.

g) The use of appropriate statistical or other techniques can help in the understanding of both processes and measurement variation, and can thereby improve process and product performance by controlling variation.

h) Self assessment should be considered on a periodic basis to assess the maturity of quality management system and the level of organization’s performance, as well as to define opportunities for performance improvement.

i) Understand how to measure the business impact of knowledge management using set of lean metrics.
8 Measurement Analyses and Improvement

General

The organization shall plan and implement the monitoring, measurements, analysis and improvement processes needed.

a) To demonstrate conformity of product.

b) To ensure conformity of the quality management system.

c) To continually improve the effectiveness of the quality management system.

d) To measure the benefits of knowledge management for convincing top management.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Measurement and Monitoring

8.2.1 Measurement and Monitoring of System Performance

8.2.1.1 General

Top management should ensure that effective and efficient methods are used to identify areas of improvement of quality management system performance.

Examples of methods include,

- Satisfaction surveys for customer and other interested parties
- Internal audits
- Financial instruments
- Self assessment
- Calculating return on investment on knowledge management investments.
8.2.1.2 Measurement and monitoring of customer satisfaction

Measurement and monitoring of customer satisfaction is based on review of customer-related information. The collection of such information may be active or passive. The organization should identify sources of customer and end-user information, available in written and verbal forms, from internal; and external sources examples of customer related information include,

- Customer and user survey
- Feedback on aspect of product
- Customer requirements and contact information
- Market needs
- Service delivery data
- Information relating to competition
- *Getting knowledge about customer expectation using information technology techniques like e-business.*

Management should use measurement of customer satisfaction via tool. The organization’s process for requesting, measuring, and monitoring feedback of customer’s satisfaction should provide information on continual basis. This process should consider, as well as the price and delivery of product.

---

**Knowledge Managed ISO 9001:2000 based Quality System-requirements**

8.2 Monitoring and measurement
8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined. *The organization shall use knowledge management techniques such as telephonic conversation with customer, to measure satisfaction of the customers.*
8.2.1.3 Internal audit

Top management should ensure the establishment of an effective and efficient internal audit process to assess the strengths and weakness of knowledge management based quality system. The internal audit process acts as a management tool for independent tool for use obtaining objective evidence that the existing requirement have been met, since the internal audit evaluates the effectiveness and efficiency of the organization.

Examples of subjects for consideration of internal auditing include,

- Effective and efficient implementation of process
- Opportunities for continual improvement
- Capability of process
- Effective and efficient of statistical techniques
- Use of information technology
- Analysis of quality cost data
- Effective and efficient use of resources
- Process and product performance results and expectations
- Adequacy and accuracy of performance measurement
- Improvement activities
- Relationship with interested parties
- Use Bohn’s stage of knowledge growth framework to measure process knowledge.

Knowledge Managed ISO 9001:2000 based Quality System-requirements
8.2.2 Internal audit
The organization shall conduct internal audits at planned intervals to determine whether the knowledge management based quality system
a) Conforms to planned arrangements, to the international standard and to the quality management system requirements established by the organization.

b) The effectively implemented and maintained.

c) *The growth knowledge in the organization.*

The management responsible for the area being audited shall ensure that action are taken without undue delay to eliminate detected non conformities and their causes, follow-up activities shall include the verification of the action taken and reporting of verification results the management responsible for measuring the growth of knowledge over a period of time, it can be used for future of the organization

### 8.2.1.4 Financial measures

Management should consider the conversion of data from processes to financial information in order to provide comparable measures across process and to facilitate improvement of the effectiveness and efficiency of the organization.

Examples of financial measures include,

- Prevention and appraisal cost analysis
- Nonconformity cost analysis
- Internal and external failure cost analysis
- Life cycle cost analysis
- *Return on investment on knowledge management.*
8.2.1.5 Self-assessment

Top management should consider establishing and implementing self-assessment. This is a careful evaluation, usually performed by organization’s own management that results in an opinion or judgment of the effectiveness and efficiency of the organization and the maturity of knowledge management based quality system. It can be used by the organization benchmark its performance against that of external organization and world-class performance. Self assessment also aids in evaluating the performance improvement of the organization, whereas the internal audit process of an organization is an independent audit used to obtain objective evidence that existing policies, procedures or requirements have been met, as it evaluates the effectiveness and efficiency of the knowledge management based quality system. The top management should assess how effectively the organization’s tacit knowledge is converted into explicit knowledge, and shared with other peoples of organization.

The range and depth of self-assessment should plan in relation to the organization’s objectives and priorities. The self-assessment approach described focuses on determining the degree of the effectiveness and efficiency of the implementation of the organization’s knowledge management based quality system. Some of the advantages of using self-assessment approach given are that,

- It is simple to understand
- It is easy to use
- It has minimal impact on the use of management resource
- It provides input for enhancing the performance of organization’s knowledge management based quality system.
Self-assessment should not be considered as an alternative to internal or external quality auditing. Use of approach described can provide management with overall view of the performance of the organization and the degree of maturity of the knowledge management based quality system. It can also provide input for identifying areas of the organization and the degree of maturity of the knowledge management based quality system. It can also provide input for identifying areas in the organization requiring performance improvement and in helping to determine priorities.

8.2.2 Measurement and Monitoring of Process

The organization should identify measurements methods and should perform measurements to evaluate process performance. The organization should incorporate these measurements in to processes and use the measurements in process management. The organization should select appropriate metrics to measure the knowledge growth.

Measurements of process performance should cover the needs and expectation of interested parties in a balanced manner. Examples include,

- Capability
- Reaction time
- Cycle time or throughput
- Measurable aspects of dependability
- Yield
- The effectiveness and efficiency of organization’s people
- Utilization of technologies
- Waste reduction
- Cost allocation and reduction
- Benchmarking.
8.2.3 Monitoring and measurement of process

The organization shall apply suitable methods for monitoring and, where applicable, measurement of knowledge management based quality system processes. These methods shall demonstrate the ability of processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate to ensure conformity of the product. The organization should have the commitment to utilize knowledge management based quality management, when any deviation from actual knowledge management based quality management it should take place.

8.2.3 Measurement and Monitoring of Product

The organization should establish and specify the measurement requirements (including acceptance criteria) for its products. The organization of product should be planned and performed in order to verify that the requirements of interested parties have been achieved and used to improve the realization processes.

When selecting measurements methods for ensuring that products confirm to requirements and considering customer needs and expectations, the organization should consider the following:

a) The type of product characteristics, which to determine the types of measurement, suitable measurement means, the accuracy required and skills needed.

b) Equipment, software and tools required.

c) The location of suitable measurement points in the realization process sequence.
d) Characteristics to be measured at each point, and documentation and acceptance criteria to be used.

e) Customer established points for witness or verification of selected characteristics of a product.

f) Inspection or testing required to be witnessed or performed by statutory and regulatory authorities.

g) Where, when and how the organization intend, or is required by the customer or statutory and regulatory authorities, to engage qualified third parties to perform

- Type testing
- In-process inspection or testing
- Product verification
- Product qualification
- Product validation

h) Qualification of people, material, products, processes, and quality management system.

i) Final inspection to confirm that verification and validation activities have been completed and accepted.

j) Recording the results of product measurements.

k) *How effectively the existing knowledge is used to get good quality product.*

The organization should review the methods used for measuring products and the planned records of verification, to consider opportunities for performance improvement. Typical examples of product measurement records that could be considered for performance improvement include,

- Inspection and test reports
- Material release notice
- Product acceptance form
- Certificate of conformity as required
- **Product service quality record.**

Knowledge Managed ISO 9001:2000 based Quality System-requirements

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristic of the product to verify that product requirement has been met. This shall be carried out at appropriate stages of the product realization stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained. Records shall be maintained. Records shall indicate the persons authorizing realize of product.

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by customer. **The management should adapt the Bohn’s framework of knowledge growth in the organization to measure the knowledge growth.**

8.2.5 Measurement and Monitoring the Satisfaction of Interested Parties

The organization should identify the measurement information required to meet the needs of interested parties (other than customers), in relation to processes of the organization in order to balance the allocation of resources, such information should include measurement relating to the people in the organization, owners and investors, suppliers and partners, as well as society. Measurement examples are follows:

a) For the people in the organization should

   Survey the opinion of its people regarding how well the organization satisfies their needs and expectation
   Assess individual and collective performance and their contribution to organizational result.
b) For owners and investor, the organization should
   Assess its capacity to attain defined objectives
   Evaluate the impact of external factors on its results
   Assess its financial performance
   Identify the value contributed by the actions taken.

c) For supplier and partner, the organization should
   Survey the opinion of supplier and partners on their
   satisfaction with purchasing processes of the organization
   Monitor and supply feedback on the performance of supplier
   and partners and their compliance with organization’s
   purchasing policy
   Assess the quality of product purchase, contribution from
   supplier and partners, and mutual benefits derived from
   relationship.

d) For society, the organization should
   Define and track suitable data relative to its objectives, in
   order to achieve satisfactory interaction with society
   Periodically assess the effectiveness and efficiency of its
   action and the perception its performance by relevant parts of
   society.

8.3 Control of Nonconformity

8.3.1 General

   Top management should empower people in the organization with
   the authority and responsibility to report nonconformities at any stage of a
   process in order to ensure timely detection and disposition of nonconformities
   should be defined to maintain achievement of process and product
   requirements. The organization should effectively and efficiently control
   nonconforming product identification, segregation and disposition in order to
   prevent misuse.
8.3.2 Nonconformity Review and Disposition

The management of an organization should ensure the establishment of an effective and efficient process to provide for review and disposition of identified nonconformities. Authorized people to determine if any trends or patterns of occurrence required attention should conduct review of nonconformities. Negative trends should be considered for improvement and as input to management review where reduction goals and resource needs are considered.

People carrying out the review should have the competence to evaluate the total effects of the nonconformity and should have the authority and resources to disposition the nonconformity and define appropriate corrective action. Acceptance of nonconformity disposition may be contractual requirement of the customer, or a requirement of other interested parties.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

8.3 Control of nonconforming products

The organization shall ensure that product with does not confirm to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be identified in a documented procedure.

The organization shall deal with nonconforming product by one or more of following ways:

a) By taking action to eliminate the detected nonconformity.

b) By authorizing its use, release or acceptance under concession by relevant authority and, where applicable, by the customer.

c) By taking action to preclude its original intended use or application.

d) Utilizing knowledge management principles to eliminate non-conformity of product.
8.4 Analysis of Data

Decisions should be based on analysis of data obtained from measurement and information collected as described in this international standard. In this context, the organization should analyze data from its various sources to assess performance against plans, objectives and other defined goals, and to identify areas for improvement including possible benefits for interested parties.

Decisions based on facts require effective and efficient actions such as,

- Valid analysis method
- Appropriate statistical techniques
- Making decision and taking actions based on results of logical analysis, as balanced with experience and intuition
- Analyze the data based upon Strength, Weakness, Opportunities and Threats (SWOT) analysis.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of knowledge management based quality system and to evaluate where continual improvement of the effectiveness of the knowledge management based quality system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) Customer satisfaction.

b) Conformity of product requirement.

c) Characteristics and trend of processes and products including opportunities for preventive action.

d) Suppliers.

e) The success of knowledge management in the organization.
8.5 Improvement

8.5.1 General

Management should continually seek to improve the effectiveness and efficiency of the processes of the organization, rather than wait for a problem to reveal opportunities for improvement. Improvements of range from small-step ongoing continual improvement to strategic break through improvement projects. The organization should have a process in place to identify and manage improvement activities. This improvement may result in change to the product or processes and even to the knowledge management based quality system or to the organization.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

8.5 Improvements
8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the knowledge management based quality system though the use of the knowledge management based quality policy, objectives, audit results, analysis of data, corrective actions, and management review.

8.5.2 Corrective Action

Top management should ensure that corrective action is used as a tool for improvement. Corrective action planning should include evaluation of the significance problem, and should be in terms of the potential impact on such aspects as opening cost, cost of nonconformity, product performance, dependability and safety and satisfaction of customers and other interested parties. People from appropriate disciplines should participate in corrective action process. Also, the effectiveness and efficiency of processes should be emphasized when actions are taken and the action should be monitored to ensure that desired goals are met. Corrective action should be considered for inclusion in management review.
In pursuing corrective action, the organization should identify sources of information, and collect information to define the necessary corrective action. The defined corrective action should be focused on eliminating causes of nonconformities in order to avoid recurrence. Examples of sources of information for corrective action consideration include,

- Customer complaints
- Nonconformity reports
- Internal audit report
- Output from management review
- Output from data analysis
- Output from Results Driven Incremental methodology.

Knowledge Managed ISO 9001:2000 based Quality System-requirements

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence corrective action shall be appropriate to the effects of the non-conformities encountered.

A document procedure shall be established to define requirements for

a) Reviewing nonconformities encountered.

b) Determining the cause of nonconformities.

c) Evaluating the need for ensure that nonconformities do not recur.

d) *Store the corrective action in the form of compact discs, which will be useful to enable the history whenever some problem arises.*

8.5.3 Loss Prevention

Management should plan mitigate the effects of loss to the organization in order to maintain the performance of processes and products. Loss prevention in the form of planning should be applied to realization and support processes, activities and product to ensure the satisfaction of interested parties.
To be effective and efficient, planning for loss prevention should be systematic. This should be based on data from appropriate methods, including evaluation of historical data for trends, and critically relative to performance of organization and its product, in order to generate data in quantitative terms. Data can be generated from,

- Use of risk analysis tools such as fault mode effect analysis
- Review of customer needs and expectation
- Management review output
- Outputs from data analysis
- Satisfaction measurement
- Processes measurement
- System that consolidate source of information from interested parties
- Relevant quality management system
- Lessons learned from past experience
- Results of self assessment
- Processes that provide early warning of approaching out-of-control operating conditions.

Knowledge Managed ISO 9001:2000 based Quality System - requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action shall be appropriate to the effects of the potential problems. Documented procedure shall be established to define requirements for

a) Determining potential nonconformities and their causes.
b) Evaluating the need for action to prevent occurrence of nonconformities.
c) Determining and implementing action needed.
d) Records of results of action taken.
e) Reviewing preventive action.
f) *Use of electronic means to aware the workers about accidents: safety measure should be taken during the operation.*
8.5.4 Continual Improvement of the Organization

To aid in ensuring the future of the organization and satisfaction of interested parties, management should create a culture, which involves people actively seeking opportunities for improvement of performance in processes, activities and products. To involve people, top management should create an environment where authority is delegated so that people are empowered and accept responsibility to identify opportunities where the organization can improve its performance.

This can be achieved by activities such as,

- Setting of objective for people, projects and the organization
- Benchmarking competitor performance and best practice
- Recognition and reward for achievement of improvement

To provide a structure for improvement activities, top management should define and implement a process for continual improvement that can be applied to realization and support process and activities.