Study the utilization of ISO 9000 software for ISO 9000 certified company in Thailand

By

Ms. Vutitorn Mahatthanawongwan

Submitted in Partial Fulfillment of
the Requirements for the Degree of
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in Technology Management
Assumption University

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Master Project Approval

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ABSTRACT

There are a lot of Thai companies that implement the Quality Management System (QMS) in the name of ISO 9000 (International Standards). To gain more competitive advantage over the competitors, the firms implement this system and try to maintain their certification.

The aim of ISO 9000 is not only to consistently provide product that meets customer and applicable regulatory requirements but also to enhance customers' satisfaction through the effective application of the system including the process for continual improvement of the system. To maintain the ISO 9000 system, the most difficulties faced by the survey of Lai, in Singapore, in 1995 are communication between management and workforce, understanding the quality system and the allocation of sufficient resources so the firms try to find technology tools such as computer software to help the management team to handle this barrier more easily.

The project aims to study the software that is used to help ISO 9000 system in Thailand, and then evaluate its performance and customer satisfaction by using primary data from software users questionnaire survey. The result of this study will show the performance of this software in the qualitative viewpoint and recommend some methods to develop the further software.

The author hopes that this project study will be useful for the existing status of ISO 9000 system software in Thailand and will encourage the concerning person to develop ISO 9000 software to improve the utilization of ISO 9000 system.

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Chapter 1 Introduction

1.1 Introduction

This project is the study of the utilization of ISO 9000 software packages for Thai ISO 9000 certified companies in Thailand.

There are 4018 companies that achieve the ISO 9000 certification in Thailand. By survey, some of them faced that the difficulties to implement and maintain ISO 9000 standard system in their company are communication between management and workforce, understanding the quality system and allocation of sufficient resources. One of the solutions to this difficulty is to use technology as a tool to help them to overcome that difficulty. To use software as a tool to maintain ISO 9000 system in Thailand is the aim of this study.

The software application to help ISO 9000 system maintaining in Thailand is not countrywide. There are few companies that use software to help their communication and maintain this Quality system compared to the companies that are certified with ISO 9000. There is only one or two commercial software packages that are well known in Thailand by Thai software house.

This study will encourage the concerning people to develop the future software for ISO 9000, to activate Thai software house and companies and to develop Thai software that is suitable for ISO 9000 certified.

To help Thai companies in Thailand make better Thai economy and trade balance and to encourage ISO 9000 certified companies in Thailand to use the technology tool (Software) to maintain and continually improve their quality system are the wishes of the author.

1.2 Purposes and objectives

In term of utilization of this software, in this project, the author will focus on the functional performance feature on ISO 9000 and customers' satisfaction survey.

The purposes of this project are to

1. Study the Thai commercial software package (ISO Master), status supporting the ISO 9000 maintaining in Thailand market to gain information to encourage the Thai ISO 9000 software development.
2. Survey the performance in feature software and customer satisfaction of the Thai commercial software package that is used in Thailand.
3. Guide and explicit the future Thai software for ISO 9000 system development in Thailand.

1.3 Scope and limitation

This study scope and limitation is

1.3.1 The survey of performance and satisfaction of the companies that use ISO Master data and some interview are used for future software discussion.

1.3.2 The software of this study focuses on commercial software package that aims to help the small and medium companies in Thailand to use this tool to maintain and continually improve this quality system.

1.3.3 The most famous software used for ISO 9000 system is ISO MASTER, because only one software package is used in Thailand.

1.3.4 The target group of companies is the group of the ISO 9000 certified companies in Thailand, especially 36 companies that use ISO MASTER for ISO 9000.

1.4 Problem statement

1.4.1 Is there any Thai commercial software package supporting the maintaining ISO 9000 Thai system of companies in Thailand?

1.4.2 Are the companies that use the software satisfied with their software?

1.4.3 Why do some companies certified by ISO 9000 not use the software to help their maintaining the system?

1.4.4 What is the key factor for the new future commercial software package for companies in Thailand?

If we can answer the above questions, the author believes that there are a lot of opportunities to develop software package that is suitable for the companies in Thailand. To fulfill the customer demand of ISO 9000 certified companies in Thailand (4018 companies) to use software (tool) to help their maintaining and continual improvement of ISO 9000 is the by gap of marketing opportunity for Thai software house for business purpose.

Thai government can use this information for supporting the IT sector to develop the software for Thai companies by Thai software house for ISO 9000 system.

Chapter 2 Existing Study

By studying this topic, we can classify it into two parts.

The first part is to study ISO 9000 version 2000 system (Quality management system; the second part is to study Thai commercial software package for ISO 9000 in Thailand market and its feature and application.

2.1 Part 1 Quality management system (QMS) 1S09001:2000

2.1.1 Why is international standardization needed?

The existence of non-harmonized standards for similar technologies in different countries or regions can contribute to so-called "technical barriers to trade". Export-minded industries have long sensed the need to agree on world standards to help rationalize the international trading process. This was the origin of the establishment of ISO.

International standardization is well-established for many technologies in such diverse fields as information processing and communications, textiles, packaging, distribution of goods, energy production and utilization, shipbuilding, banking and financial services. It will continue to grow in importance for all sectors of industrial activity for the foreseeable future.

The main reasons are:

- *Worldwide progress in trade liberalization*

  Today's free-market economy increasingly encourages diverse sources of

supply and provide opportunities for expanding markets. On the technology side, fair competition needs to be based on identifiable, clearly defined common references that are recognized from one country to the next, and from one region to the other. An industry-wide standard, internationally recognized, developed by consensus among trading partners, serves as the language of trade.

- *Interpenetration of sectors*

  No industry in today's world can truly claim to be completely independent of components, products, rules of application, etc., that have been developed in other sectors. Bolts are used in aviation and for agricultural machinery; welding plays a role in mechanical and nuclear engineering, and electronic data processing has penetrated all industries. Environmentally friendly products and processes, and recyclable or biodegradable packaging are pervasive concerns.

- *Worldwide communications systems*

  The computer industry offers a good example of technology that needs quickly and progressively to be standardized at a global level. Full compatibility among open systems fosters healthy competition among producers, and offers real options to users since it is a powerful catalyst for innovation, improved productivity and cost-cutting.

- *Global standards for emerging technologies*

  Standardization program in completely new fields are now being developed. Such fields include advanced materials, the environment, life

sciences, urbanization and construction. In the very early stages of new technology development, applications can be imagined but functional prototypes do not exist. Here, the need for standardization is in defining terminology and accumulating databases of quantitative information.

- *Developing countries*

  Development agencies are increasingly recognizing that a standardization infrastructure is a basic condition for the success of economic policies aimed at achieving sustainable development. Creating such an infrastructure in developing countries is essential for improving productivity, market competitiveness, and export capability.

Industry-wide standardization is a condition existing within a particular industrial sector when the large majority of products or services conforms to the same standards. It results from consensus agreements reached between all economic players in that industrial sector - suppliers, users, and often governments. They agree on specifications and criteria to be applied consistently in the choice and classification of materials, the manufacture of products, and the provision of services. The aim is to facilitate trade, exchange and technology transfer through:

- enhanced product quality and reliability at a reasonable price;
- improved health, safety and environmental protection, and reduction of waste;
- greater compatibility and interoperability of goods and services;
- simplification for improved usability;
- reduction in the number of models, and thus reduction in costs;

- increased distribution efficiency, and ease of maintenance.

Users have more confidence in products and services that conform to International Standards. Assurance of conformity can be provided by manufacturers' declarations, or by audits carried out by independent bodies.

2.1.2 The ISO 9000 family

The standards, guidelines and technical reports which make up the ISO 9000 family and which are listed below are available separately, or as collections. The ISO 9000 Compendium presents the ISO 9000 family in hard copy form.

Table 2-1 Standards and guideline and their purposes

Source: www.iso.ch

Standards and guidelines	Purpose
ISO 9000:2000, *Quality management systems - Fundamentals and vocabulary*	Establishes a starting point for understanding the standards and defines the fundamental terms and definitions used in the ISO 9000 family which you need to avoid misunderstandings in their use.
ISO 9001:2000, *Quality management systems - Requirements*	This is the requirement standard you use to assess your ability to meet customer and applicable regulatory requirements and thereby address customer satisfaction. It is now the only standard in the ISO 9000 family against which third-party certification can be carried.

Table 2-1 Standards and guideline and their purposes

Source : www.iso.ch

ISO 9004:2000, *Quality management systems - Guidelines for performance improvements*	This guideline standard provides guidance for continual improvement of your quality management system to benefit all parties through sustained customer satisfaction.
ISO 19011, *Guidelines on Quality and/or Environmental Management Systems Auditing* (currently under development)	Provides you with guidelines for verifying the system's ability to achieve defined quality objectives. You can use this standard internally or for auditing your suppliers.
ISO 10005:1995, *Quality management - Guidelines for quality plans*	Provides guidelines to assist in the preparation, review, acceptance and revision of quality plans.
ISO 10006:1997, *Quality management - Guidelines to quality in project management*	Guidelines to help you ensure the quality of both the project processes and the project products.
ISO 10007:1995, *Quality management - Guidelines for configuration management*	Gives you guidelines to ensure that a complex product continues to function when components are changed individually.

Table 2-1 Standards and guideline and their purposes

Source : www.iso.ch

Standards and guidelines	Purpose
ISO/DIS 10012, *Quality assurance requirements for measuring equipment* - Part 1: *Metrological confirmation system for measuring equipment*	Gives you guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy.
ISO 10013:1995, *Guidelines for developing quality manuals*	Provides guidelines for the development, and maintenance of quality manuals, tailored to your specific needs.
ISO/TR 10014:1998, *Guidelines for managing the economics of quality*	Provides guidance on how to achieve economic benefits from the application of quality management.
ISO 10015:1999, *Quality management - Guidelines for training*	Provides guidance on the development, implementation, maintenance and improvement of strategies and systems for training that affects the quality of products.
ISO/TS 16949:1999, *Quality systems - Automotive suppliers - Particular requirements for the application of ISO 9001:1994*	Provides specific guidance to the application of ISO 9001 in the automotive industry.

2.2 Quality management principles

The following text is an integral reproduction of the content of the document "Quality Management Principles".

This document introduces the eight quality management principles on which the quality management system standards of the revised ISO 9000:2000 series are based. Senior management as a framework to guide their organizations towards improved performance can use these principles. The principles are derived from the collective experience and knowledge of the international experts who participate in ISO Technical Committee ISO/TC 176, *Quality management and quality assurance*, which is responsible for developing and maintaining the ISO 9000 standards.

The eight quality management principles are defined in ISO 9000:2000, *Quality management systems Fundamentals and vocabulary,* and in ISO 9004:2000, *Quality management systems Guidelines for performance improvements.*

This document gives the standardized descriptions of the principles as they appear in ISO 9000:2000 and ISO 9004:2000. In addition, it provides examples of the benefits derived from their use and of actions that managers typically take in applying the principles to improve their org nizations' performance.

- Principle 1 Customer focus
- Principle 2 Leadership
- Principle 3 Involvement of people
- Principle 4 Process approach

- Principle 5 System approach to management
- Principle 6 Continual improvement
- Principle 7 Factual approach to decision making
- Principle 8 Mutually beneficial supplier relationships
- The next step

2.2.1 Principle 1 Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Key benefits:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organization's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.

Applying the principle of customer focus typically leads to:

- Researching and understanding customer needs and expectations.
- Ensuring that the objectives of the organization are linked to customer needs and expectations.
- Communicating customer needs and expectations throughout the organization.
- Measuring customer satisfaction and acting on the results.
- Systematically managing customer relationships.

- Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

2.2.2 Principle 2 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.

Key benefits:

- People will understand and be motivated towards the organization's goals and objectives.
- Activities are evaluated, aligned and implemented in a unified way.
- Miscommunication between levels of an organization will be minimized.

Applying the principle of leadership typically leads to:

- Considering the needs of all interested parties including customers, owners, employees, suppliers, financiers, local communities and society as a whole.
- Establishing a clear vision of the organization's future.
- Setting challenging goals and targets.
- Creating and sustaining shared values, fairness and ethical role models at all levels of the organization.
- Establishing trust and eliminating fear.
- Providing people with the required resources, training and freedom to act with responsibility and accountability.

- Inspiring, encouraging and recognizing people's contributions.

2.2.3 Principle 3 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.

Key benefits:

- Motivated, committed and involved people within the organization.
- Innovation and creativity in furthering the organization's objectives.
- People being accountable for their own performance.
- People eager to participate in and contribute to continual improvement.

Applying the principle of involvement of people typically leads to:

- People understanding the importance of their contribution and role in the organization.
- People identifying constraints to their performance.
- People accepting ownership of problems and their responsibility for solving them.
- People evaluating their performance against their personal goals and objectives.
- People actively seeking opportunities to enhance their competence, knowledge and experience.
- People freely sharing knowledge and experience.
- People openly discussing problems and issues.

2.2.4 Principle 4 Process approach

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

Key benefits:

- Lower costs and shorter cycle times through effective use of resources.
- Improved, consistent and predictable results.
- Focused and prioritized improvement opportunities.

Applying the principle of process approach typically leads to:

- Systematically defining the activities necessary to obtain a desired result.
- Establishing clear responsibility and accountability for managing key activities.
- Analyzing and measuring of the capability of key activities.
- Identifying the interfaces of key activities within and between the functions of the organization.
- Focusing on the factors such as resources, methods, and materials that will improve key activities of the organization.
- Evaluating risks, consequences and impacts of activities on customers, suppliers and other interested parties.

2.2.5 Principle 5 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.

Key benefits:

- Integration and alignment of the processes that will best achieve the desired results.

- Ability to focus effort on the key processes.
- Providing confidence to interested parties as to the consistency, effectiveness and efficiency of the organization.

Applying the principle of system approach to management typically leads to:

- Structuring a system to achieve the organization's objectives in the most effective and efficient way.
- Understanding the interdependencies between the processes of the system.
- Structured approaches that harmonize and integrate processes.
- Providing a better understanding of the roles and responsibilities necessary for achieving common objectives and thereby reducing cross-functional barriers.
- Understanding organizational capabilities and establishing resource constraints prior to action.
- Targeting and defining how specific activities within a system should operate.
- Continually improving the system through measurement and evaluation.

2.2.6 Principle 6 Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

Key benefits;

- Performance advantage through improved organizational capabilities.
- Alignment of improvement activities at all levels to an organization's strategic intent.
- Flexibility to react quickly to opportunities.

Applying the principle of continual improvement typically leads to:

- Employing a consistent organization-wide approach to continual improvement of the organization's performance.
- Providing people with training in the methods and tools of continual improvement.
- Making continual improvement of products, processes and systems an objective for every individual in the organization.
- Establishing goals to guide, and measures to track, continual improvement.
- Recognizing and acknowledging improvements.

2.2.7 Principle 7 Factual approach to decision making

Effective decisions are based on the analysis of data and information

Key benefits:

- Informed decisions.
- An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.
- Increased ability to review, challenge and change opinions and decisions.

Applying the principle of factual approach to decision making typically leads to:

- Ensuring that data and information are sufficiently accurate and reliable.
- Making data accessible to those who need it.
- Analyzing data and information using valid methods.
- Making decisions and taking action based on factual analysis, balanced with experience and intuition.

2.2.8 Principle 8 Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

Key benefits:

- Increased ability to create value for both parties.
- Flexibility and speed of joint responses to changing market or customer needs and expectations.
- Optimization of costs and resources.

Applying the principles of mutually beneficial supplier relationships typically leads to:

- Establishing relationships that balance short-term gains with long-term considerations.
- Pooling of expertise and resources with partners.
- Identifying and selecting key suppliers.
- Clear and open communication.
- Sharing information and future plans.
- Establishing joint development and improvement activities.
- Inspiring, encouraging and recognizing improvements and achievements by suppliers.

This document provides a general perspective on the quality management principles underlying the ISO 9000:2000 series. It gives an overview of these principles and shows how, collectively, they can form a basis for performance improvement and organizational excellence.

There are many different ways of applying these quality management principles. The nature of the organization and the specific challenges it faces will determine how to implement them. Many organizations will find it beneficial to set up quality management systems based on these principles.

The requirements of quality management systems and supporting guidelines are given in the ISO 9000 - Selection and use.

Further information on the ISO 9000 standards is available from ISO's national member institutes or from the ISO Central Secretariat ISO 9000 enquiry service. Sales enquiries should also be directed to the ISO members or to the ISO Central Secretariat sales department.

ISO publishes the bimonthly *ISO Management Systems*, which provides updates on these families of standards and news on their implementation around the world. A Spanish-language edition is published by the Spanish national standards institute, AENOR.

2.3 Guidance on the Process Approach to Quality Management Systems

Document ISO/TC 176/SC 2/N544R

May 2001

This guidance document is intended to help users of the ISO 9000:2000 series of standards to understand the concepts and intent of the "process approach" to quality management systems. It is not limited to the requirements of ISO 9001:2000, and is not intended to provide guidance for conformity assessment purposes. It should not be interpreted as a source of additional requirements to those contained in ISO 9001:2000.

The new ISO 9000:2000 standards promote the adoption of a process approach when developing, implementing and improving a quality management system (QMS). The process approach is reflected in the structure of ISO 9004:2000, *Quality Management Systems - Guidelines for performance improvement*, and also in ISO 9001:2000, *Quality management systems - Requirements.* The "20 element" structure of ISO 9001:1994 has

been replaced by this process-based quality management system, which is shown schematically in Figure 1 below.

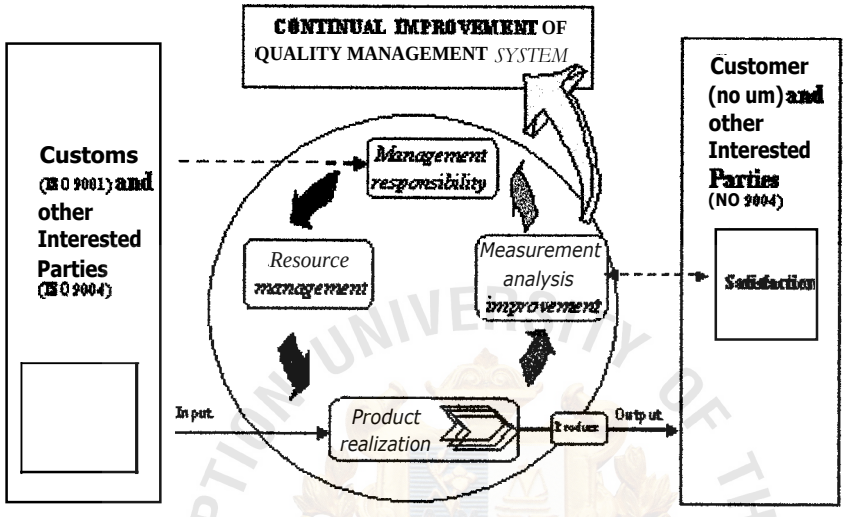

Figure 2-1 Model of a process-based quality management system (Taken from ISO 9000:2000)

Source : www.iso.ch

This guidance document seeks to explain, in simple language, what is meant by a process, how processes can interact within a system, and how the Plan-Do-Check-Act (PDCA) cycle can be used to manage those processes. Examples of quality management system processes are given, as well as guidance on the implementation of the process approach in relation to ISO 9001:2000 requirements.

23.1 Understanding the Process Approach

One of the eight quality management principles on which the ISO 9000:2000 series of standards is based relates to the "Process Approach" as follows:

Process Approach: a desired result is achieved more efficiently when activities and related resources are managed as a process.

ISO 9000:2000 clause 3.4.1 defines a "**Process**" as:

"Set of interrelated or interacting activities which transforms inputs into outputs

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Processes in an ***organization*** *(3.3.1) are generally planned and carried out under controlled conditions to add value."*

Inputs and outputs may be tangible or intangible. Examples of inputs and outputs may include equipment, materials, components, energy, information and financial resources, among others. To perform activities within the process appropriate resources have to be allocated. A measurement system can be used to gather information and data to analyse process performance and input and output characteristics.

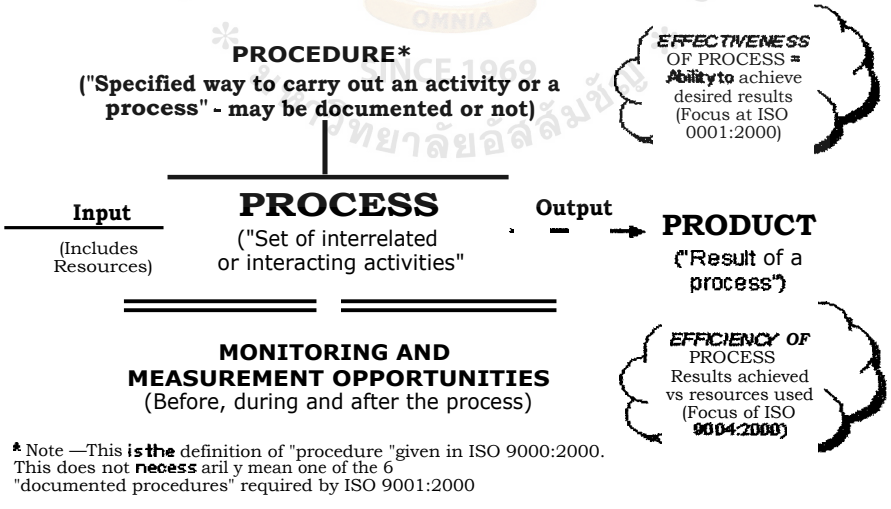

Fig 2-2 Schematic representation of a Process

Source : www.iso.ch

ISO 9001:2000 stresses the importance for an organization to identify, implement, manage and continually improve the effectiveness of the processes that are necessary for the quality management system, and to manage the interactions of these processes in order to achieve the organization's objectives. ISO 9004:2000 guides the organization beyond the requirements of ISO 9001:2000 by focusing on performance improvements. ISO 9004:2000 recommends an evaluation of the efficiency, as well as the effectiveness of the processes.

Process effectiveness and efficiency can be assessed through internal or external review processes and be evaluated on a maturity scale. These scales typically range in degrees of maturity from "no formal system" to "best-in-class performance". An advantage to this approach is that results can be documented and monitored over time to reach improvement goals. Numerous maturity tables have been developed for different applications. One such model is contained in ISO 9004:2000 Annex A, *Guidelines for Self-Assessment.*

2.3.2 The P-D-C-A Cycle and the process approach

The "Plan-Do-Check-Act" cycle was first developed in the 1920's by Walter Shewhart, and was popularized later by W. Edwards Deming. For that reason it is often referred to as "The Deming Cycle". Extensive literature exists about the PDCA cycle in numerous languages, and users of the ISO 9000:2000 family of standards are encouraged to consult this for a deeper understanding of the concept.

The PDCA concept is something that is present in all areas of our professional and personal lives, and is used continually, either formally or informally, consciously or sub-

consciously in everything we do. Every activity, no matter how simple or how complex, falls into this never-ending pattern:

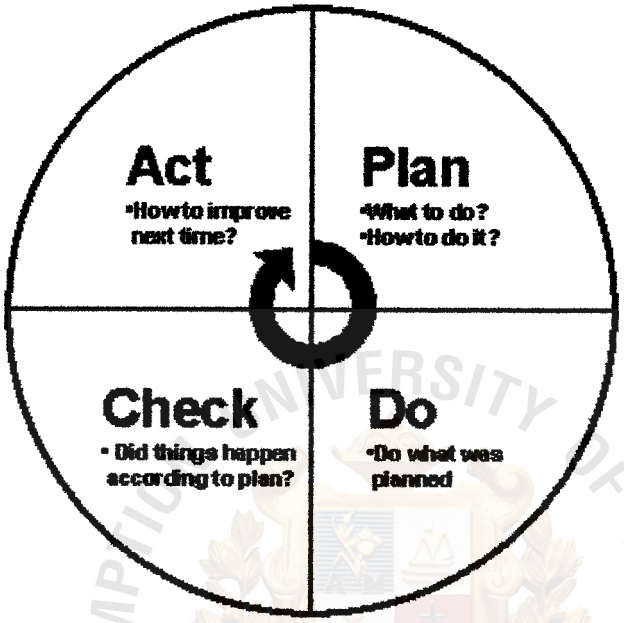

Figure 2-3 The "Plan-Do-Check-Act" cycle 1

Source : www.iso.ch

Within the context of a quality management system, the PDCA is a dynamic cycle that can be deployed within each of the organization's processes, and to the system of processes as a whole. It is intimately associated with the planning, implementation, control and continual improvement of both product realization and other quality management system processes.

Maintaining and continually improving the process capability can be achieved by applying the PDCA concept at all levels within the organization. This applies equally to high-level strategic processes, such as quality management system planning, or

management review, and to simple operational activities carried out as a part of product realization processes.

The Note in Clause 0.2 of ISO 9001:2000 explains that the PDCA cycle applies to processes as follows:

"Plan" *establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies;*

"Do" *implement the processes;*

"Check" *monitor and measure processes and product against policies, objectives and requirements for the product and report the results;*

"Act" *take actions to continually improve process performance;"*

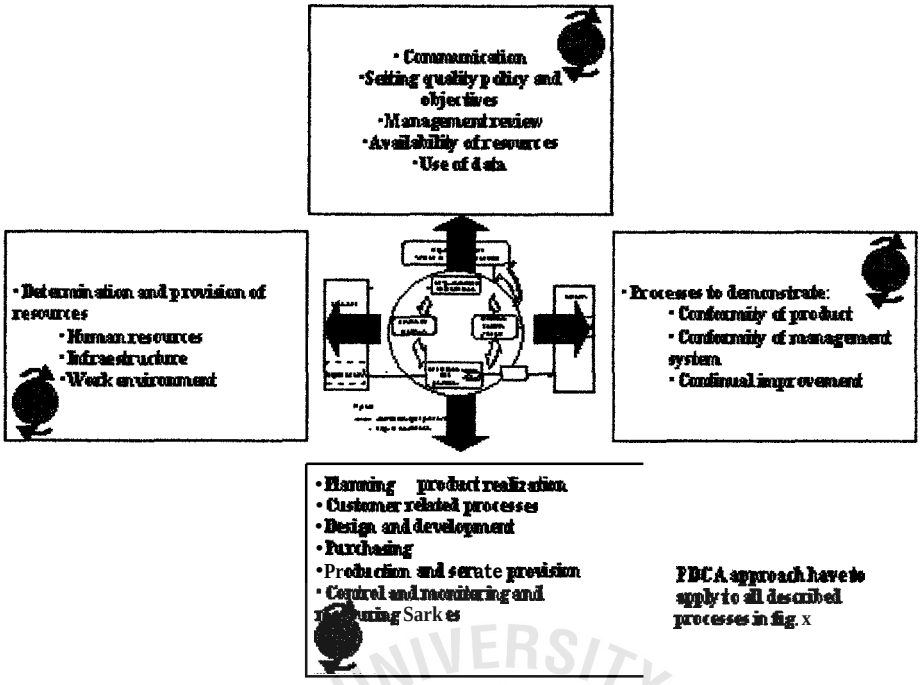

Figure 2-4 The "Plan-Do-Check-Act" **cycle 2**

Source : www.iso.ch

2.3.3 Understanding the system approach **to management**

A second important quality management principle that **is intimately linked with the** Process Approach is the System Approach **to Management, which states that** "Identifying, understanding and managing interrelated processes **as a system contributes** to the organization's effectiveness and efficiency in achieving its **objectives." Within this** context, the quality management system comprises a number of interrelated **processes.** The processes needed for the quality management system include not only the **product** realization processes (those that directly contribute to making the product or delivering the service), but also numerous management, monitoring and measurement processes, such as resource management, communication, internal auditing, management review, and other processes. This can be seen schematically in Figure 3, which provides greater

detail of the kind of processes that typically comprise the quality management system, divided among clauses 4 - 8 of ISO 9001:2000 and ISO 9004:2000.

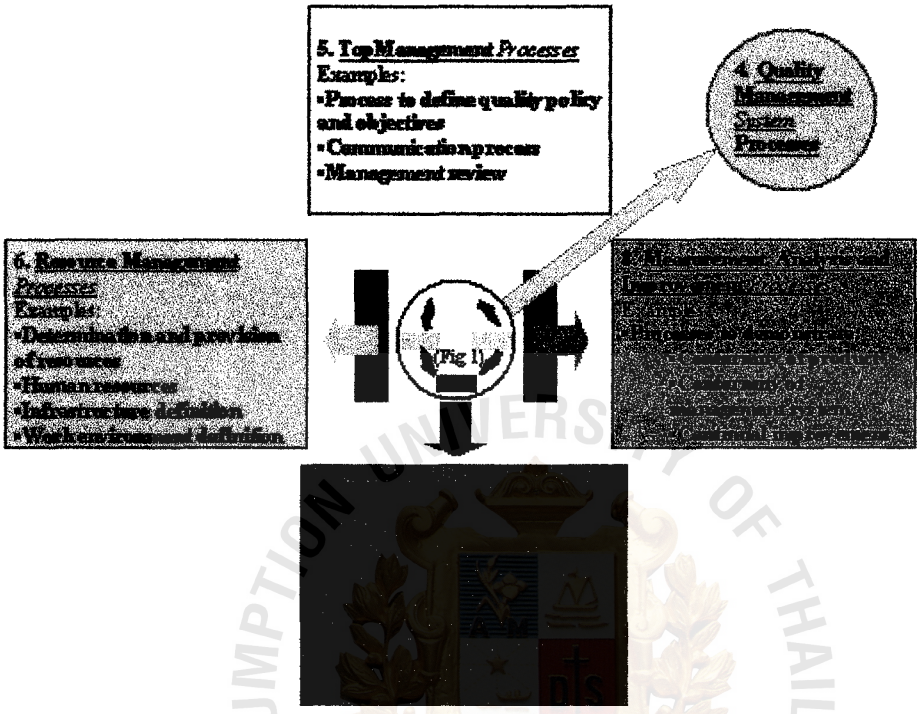

Figure 2-5 Schematic representation of typical quality management system processes, related to Figure 1

Source : www.iso.ch

Individual processes rarely occur in isolation. Outputs from one process typically form part of the inputs into subsequent processes, as shown in Figure 4.

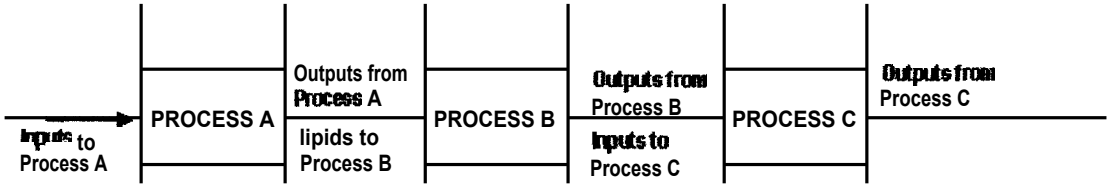

Figure 2-6 Chain of interrelated processes

Source : www.iso.ch

The interactions between an organization's processes can often be complex, resulting in a network of interdependent processes. Inputs and outputs of these processes can often be related to both external and internal customers. An example of a network with interacting processes is shown in Figure 6. The model of the network of processes illustrates that customers play a significant role in defining requirements as inputs. Customer's feedback on satisfaction or dissatisfaction of process output is an essential input to the continual improvement process of the QMS.

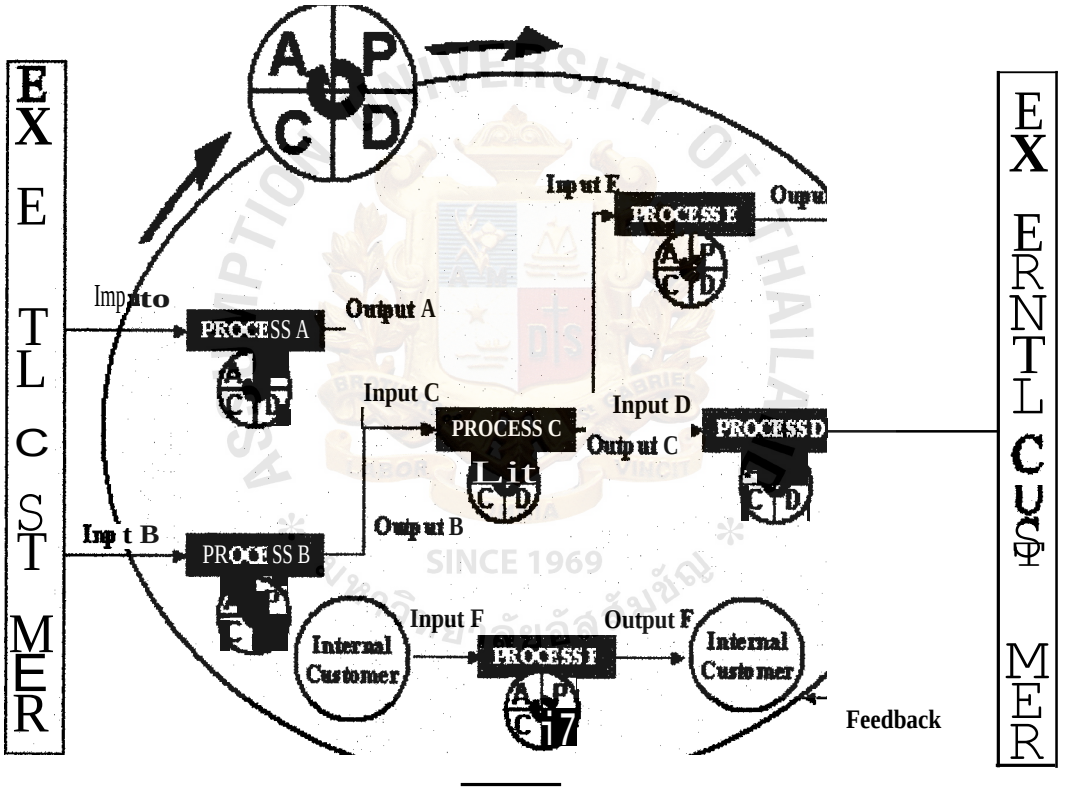

Figure 2-7 Typical network of interacting processes

Source : www.iso.ch

Note that the PDCA cycle can be applied to each individual process, as well as to the network of processes as a whole. Some important quality management system processes may have no direct interaction with the external customer. Process "F" in Figure 6, for example, may be an internal audit, a management review, maintenance, or a training process.

2.3.4 Implementation of the Process Approach in relation to ISO 9001:2000 Requirements

Clause 0.2 in the introduction of ISO 9001:2000 states, referring to the process approach:

"When used within a quality management system process, such an approach emphasizes the importance of

a) the understanding and meeting of requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement."

Further guidance is provided in clause 2.3 of ISO 9000:2000.

Within the context of ISO 9001:2000, the process approach includes the processes needed for product realization, and the other processes needed for the effective implementation of the quality management system, such as the internal audit ***process,*** the management review ***process,*** the data analysis ***process,*** and the resource management ***process,*** among others. All processes can be managed by using the "PDCA" concept.

Requirements for these processes are stated in the following clauses of ISO 9001:2000:

- 4 Quality management system
- 5 Management responsibility

- 6 Resource management
- 7 Product realization
- 8 Measurement, analysis and improvement

The general requirements for a quality management system are defined in clause 4.1 of ISO 9001:2000. Some guidance is given below on what questions an organization may choose to ask itself in order to address these requirements. It is stressed that these questions are only examples, and should ***not*** be interpreted as the only way to meet the requirements:

a) Identify the processes needed for the quality management system, and their application throughout the organization.

- What are the processes needed for our quality management system?
- Who are the customers of each process (internal and/or external customers)?
- What are the requirements of these customers?
- Who is the "owner" of the process?
- Are any of these processes outsourced?
- What are the inputs and outputs for each process?

b) Determine the sequence and interaction of these processes.

- What is the overall flow of our processes?
- How can we describe this? (Process maps or flow charts?)
- What are the interfaces between the processes?
- What documentation do we need?

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

- What are the characteristics of intended and unintended results of the process?

- What are the criteria for monitoring, measurement and analysis?

- How can we incorporate this into the planning of our QMS and product realization processes?

- What are the economic issues (cost, time, waste, etc.)?

- What methods are appropriate for data gathering?

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

- What are the resources needed for each process?

- What are the communication channels?

- How can we provide external and internal information about the process?

- How do we obtain feedback?

- What data do we need to collect?

- What records do we need to keep?

e) Measure, monitor and analyze these processes.

- How can we monitor process performance (Process capability, customer satisfaction)?

- What measurements are necessary?

- How can we best analyze gathered information (Statistical techniques)?

- What does the result of this analysis tell us?

j) Implement action necessary to achieve planned results and continual improvement of these processes

- How can we improve the process?
- What corrective and/or preventive actions are necessary?
- Have these corrective/preventive actions been implemented?
- Are they effective?

2.3.5 Documentation of processes

Processes exist within the organization and the initial approach should be limited to identifying and managing them in the most appropriate way. ISO 9001:2000 requires that all processes "needed for the quality management system" be managed according to clause 4.1 *General requirements*. There is no "catalogue", or list of processes that has to be documented. Each organization should determine which processes are to be documented on the basis of its customer and applicable regulatory or statutory requirements, the nature of its activities, and its overall corporate strategy.

In determining which processes should be documented the organization may wish to consider factors such as:

- effect on quality;
- risk of customer dissatisfaction
- statutory and/or regulatory requirements
- economic risk
- effectiveness and efficiency
- competence of personnel
- complexity of processes

Where it is found necessary to document processes, a number of different methods can be used, such as graphical representations, written instructions, checklists, flow charts, visual media, or electronic methods.

2.4 Implementing your ISO 9001:2000 quality management system

2.4.1 Identify the goals you want to achieve

Typical goals may be:

- Be more efficient and profitable
- Produce products and services that consistently meet customer requirements
- Achieve customer satisfaction
- Increase market share
- Maintain market share
- Improve communications and morale in the organization
- Reduce costs and liabilities
- Increase confidence in the production system

2.4.2 Identify what others expect of you

These are the expectations of interested parties (stakeholders) such as:

- Customers and end users
- Employees
- Suppliers
- Shareholders
- Society

2.4.3 Obtain information about the ISO 9000 family

- For general information, refer to this brochure
- For more detailed information, see ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000
- For supporting information, refer to the ISO Web site
- For implementation case studies and news of ISO 9000 developments worldwide, read the ISO publication *ISO Management Systems.*

2.4.4 Apply the ISO 9000 family of standards in your management system.

Decide if you are seeking certification that your quality management system is in conformance with ISO 9001:2000 or if you are preparing to apply for a national quality award.

- Use ISO 9001:2000 as the basis for certification
- Use ISO 9004:2000 in conjunction with your national quality award criteria to prepare for a national quality award

2.4.5 Obtain guidance on specific topics within the quality management system

These topic-specific standards are:

- ISO 10006 for project management
- ISO 10007 for configuration management
- ISO 10012 for measurement systems
- ISO 10013 for quality documentation
- ISO/TR 10014 for managing the economics of quality

- ISO 10015 for training
- ISO/TS 16949 for automotive suppliers
- ISO 19011 for auditing

2.4.6 Establish your current status, determine the gaps between your quality management system and the requirements of ISO 9001:2000

You may use one or more of the following:

- Self assessment
- Assessment by an external organization

2.4.7 Determine the processes that are needed to supply products to your customers

Review the requirements of the ISO 9001:2000 section on Product Realization to determine how they apply or do not apply to your quality management system including;

- Customer related processes
- Design and/or development
- Purchasing
- Production and service operations
- Control of measuring and monitoring devices

2.4.8 Develop a plan to close the gaps in step 6 and to develop the processes in step 7

Identify actions needed to close the gaps, allocate resources to perform these actions, assign responsibilities and establish a schedule to complete the needed actions. ISO 9001:2000 Paragraphs 4.1 and 7.1 provide the information you will need to consider when developing the plan.

2.4.9 Carry out your plan

Proceed to implement the identified actions and track progress to your schedule

2.4..10 Undergo periodic internal assessment

Use ISO 19011 for guidance in auditing, auditor qualification and managing audit program

2.4.11 Do you need to demonstrate conformance?

If yes, go to step 12

If no, go to step 13

You may need or wish to show conformance (certification/registration) for various purposes, for example:

- Contractual requirements
- Market reasons or customer preference
- Regulatory requirements
- Risk management

- To set a clear goal for your internal quality development (motivation)

2.4.12 Undergo independent audit

Engage an accredited registration/certification body to perform an audit and certify that your quality management system complies with the requirements of ISO 9001:2000.

2.4.13 Continue to improve your business

Review the effectiveness and suitability of your quality management system. ISO 9004:2000 provides a methodology for improvement.

2.5 Maintaining the benefits and continual improvement

Most new users obtain measurable benefits early in the process of deploying the standard requirements in their operations. These initial benefits are generally due to improvements in their organization and internal communication. The benefits must be strengthened through effective internal auditing and management review of system performance. Like all systems, it either improves or becomes less effective. It does not remain static for long. When you adopt ISO 9001:2000, you must strive for the satisfaction of your customers and the continual improvement of your quality management system. Continual improvement is a process of increasing the effectiveness of your organization to fulfill your quality policy and your quality objectives. ISO 9001:2000 requires that you plan and manage the processes necessary for the continual improvement of your quality management system. ISO 9004:2000 provides information that will be helpful in going beyond ISO 9001:2000 to improving the efficiency of your operation. It is recommended

that you obtain data from various sources, both internal and external, to assess the appropriateness of your quality system goals. This information can also be used to improve the performance of your processes.

2.5.1 The future evolution of ISO 9000

In order for the ISO 9000 family to maintain its effectiveness, the standards are periodically reviewed in order to benefit from new developments in the quality management field and also from user feedback. ISO/TC 176, which is made up of experts from businesses and other organizations around the world, who monitor the use of the standards to determine how they can be improved to meet user needs and expectations when the next revisions are due in approximately five years' time.

ISO/TC 176 will continue to integrate quality assurance, quality management, sector specific initiatives and various quality awards within the ISO 9000 family.

ISO's commitment to sustaining the ISO 9000 momentum through reviews, improvement and streamlining of the standards guarantees that your investment in ISO 9000 today will continue to provide effective management solutions in the future.

2.5.2 Benefits of Certification/Registration

According to survey by Lai (1995), the following are some of the key factors that influence companies to implement a quality management system and get it certified to ISO 9000 standards: Table 2-1 summarizes the relative importance of these benefits.

a) To make products more acceptable internationally, as there is a nearly unanimous worldwide acceptance of the ISO 9000 series as the quality system standards.

b) To enable a company to expert to Europe where ISO 9000 certification is expected. The creation of a single and integrated market in the European Union (EU) makes it the largest trade market in the free world.

c) To satisfy customer contractual requirements.

d) To reduce the number of second party audits.

e) To gain a competitive advantage by improving the quality of products and services through ISO 9000.

f) To improve returns on investment through correct use of operating procedures equipment, customer complaint procedures preventive and corrective actions.

g) To sustain competitiveness through the continuous quality improvement loop provided by the ISO quality system.

h) To improve communications between all levels of personnel resulting in higher staff morale as well as communications with customers and suppliers to improve efficiency.

i) To harmonize product/service and business practices worldwide.

Table 2-2, Benefits Obtained for Achieving ISO 9000 Certification

Source: IRCA REG.ISO 9000:2000 Training document

Factor	Benefits (Mean)
Securing New/Present Market	
1. Secure export opportunities to European market	3.08
2. Secure export opportunities to other markets	2.93
Improve Competitive Position	
3. Improve Competitive position	3.48
Practical Benefits	
7. Improve quality consciousness	3.66
8. Improve existing quality system	3.88
9. Provide documentation of existing quality system	3.86
10. Reduce quality problems	3.42
11. Improve process	3.31
12. Help to attain TQM	3.27
13. Achieve better teamwork and cooperation among	3.34
employees	3.30
14. Reduce rework and wastage	3.42
15. Improve communications among employees	2.95
16. Improve productivity	2.85
17. Reduce costs	2.92
18. Improve morale of employees	2.97
19. Reduce in supplier quality audits by customers	2.77
20. Increase in profits	2.77

5-Critical Important 4-Very-Important 3-Good to have 2-Not Important 1-Disagree

2.5.3 Difficulties of ISO 9000 Implementation

The difficulties encountered during ISO 9000 implementation, obtained in a survey by Lai (1995) is summarized in Table 2-2. Support and commitment of the top management is the most critical factor for the success of the ISO 9000 implementation while understanding the quality system and the allocation of sufficient resources are the most difficult factors faced by the companies. Understanding the ISO quality system depends on the degree of similarity of the existing system to ISO 9000 quality system. Allocation of resources depends on the size of the company. It is usually easier for a larger company to allocate sufficient resources.

Table 2-3, Critical Success Factors and Difficulties Faced When Implementing ISO 9000 Standards (Lai, 1995)

Source: IRCA REG.ISO 9000:2000 Training document

Factors	**Importance (Scale of 1 to 5) (Mean)**	**Difficulties (Scale of 1 to 5) (Mean)**
Getting the support and commitment of top management	4.73	2.83
Getting the support and commitment of middle management	4.58	3.27
Getting the support and commitment of workforce	4.40	3.44
Proper documentation of processes	4.36	3.51
Sustained enthusiasm of top management	4.32	3.24
Sustained enthusiasm of middle management	4.28	3.37
Understanding the quality systems	4.22	3.59
Sustained enthusiasm of workforce	4.15	3.51
Good communication between management and workforce	4.07	3.59
Allocation of sufficient resources	4.07	3.59
Extra time spent on training and meetings	3.96	3.54
Tangible improvement in sales/profits	3.24	3.43
Achieved cost savings	3.22	3.48

5-Critically Important 4-Very Important 3-Good to have 2-Not Important 1-Disagree

5-Very Difficult 4-Quite Difficult 3-Quite Easy 2-Very Easy 1-No Effort

2.6 Part two Software for QMS in Thailand

There are a lot of software in Thailand for the QMS quality management system. The most famous one is ISO Master by Business solution provider Company limited for support the ISO 9000 system. This company is IBM alliances.

IBM, Lotus and BSP offer state-of-the-art technology ISO Master software will globalize Thai industry.

An electronic document system of ISO standard will replace regular documents. Manuals are compiled and sent to users via an electronic system give a paperless office and to preserve the environment. 23 August 2001... IBM Thailand Limited, in co-operation with Business Solutions Provider Company Limited (BSP), an IBM partner, presented the state-of-the-art ISO Master software project, a paperless office system which will help preserve the environment.

The ISO Master project, using Lotus Notes technology from IBM, is meant to control and circulate electronic documents, as well as to follow up and check or approve documents within the scope of the ISO international standards system. This was jointly announced by Mrs. Jadesada Kraisingkorn, Country Manager, Software Market, IBM Thailand and Mr.Vorasit Vinkomin, Managing Director, Business Solutions Provider Company Limited. Mrs. Jadesada Kraisingkorn, Country Manager, Software Market, IBM Thailand, said: "IBM has software technologies that can be widely adapted to a variety of industries. In particular, we have Lotus Notes technology which will increase the effectiveness of

organizational information management. Notes is a world-class messaging and collaboration used by over 80 million users worldwide and can be adapted to all organizations. Our customers, Petroleum Authority of Thailand and Rayong Electricity Generating Company Limited, now have more efficient systems in their organizations through the use of ISO Master system."Mr.Vorasit Vinkomin, Managing Director of BSP, added: "ISO Master application benefits organizations costs associated with the filing and indexing, as well as routing of paper documents. With ISO Master, these mundane tasks can be done faster, more easily and in a space-saving manner through electronic means."ISO or International Organization for Standardization, sets out operational guidelines for organizations to meet in fulfillment of client delivery and satisfaction. To support this requirement, a digital communication system and perfect filing system, providing the easiest way to check and retrieve information, are the keys to success for the effective organization. Technology will improve organizational operating systems, thereby benefiting the organization. ISO Master is a software application developed from Lotus Notes technology, a world-class messaging and collaboration software from IBM. Based on Notes, ISO Master is quality solution offering scalability, collaboration capabilities for business needs, and a secure data transfer system. Using ISO Master, organizations will have a simplified deployment solution to help improve workflow performance, shorten the working cycle and allow their staff to focus on other activities thereby improving service quality. About Business Solutions Business Solutions Provider Company Limited developed ISO Master - the first-ever ISO application by a Thai developer - to control and circulate electronic documents, as well as

to follow-up and check or approve documents within the scope of the ISO international standards system.

About Lotus Development Corp.

Lotus Development Corporation, founded in 1982, is a subsidiary of IBM Corporation. Lotus sets the standard for truly innovative software products and services that reflect the company's unique understanding of the new ways in which individuals and businesses must work together to achieve success. Lotus is redefining the concept of conducting business through practical knowledge management, e-business and other ground-breaking ways of connecting the world's ideas, thinkers, buyers, sellers and communities via the Internet. Lotus markets its products in more than 80 countries worldwide through direct and extensive Business Partner channels. The company also provides numerous professional consulting, support and education services through the Lotus Professional Services organization. For business enquiry on Lotus Notes, please contact IBM.com Sales Center. Telephone: 0-2273-4444 Press contact: IBM Thailand Co., Ltd.

Chujit Wattanalumlerd Tel: 0-2273-4306 email: chujit@th.ibm.com

Krisana Sinprasert Tel: 0-2273-4639 email: krisana@th.ibm.com

2.7 Lotus Notes

Lotus Notes continues to set the standard for messaging and groupware. Now in its fourth full release, Notes has established a large and growing base of more than 3.3 million users, and has generated an expanding industry of over 12,000 business partners building Notes solutions.

Lotus Notes gives users the power to communicate within and beyond an organization. It connects users with suppliers, customers and partners at other companies using different e-mail systems or over the Internet.

With the power of Lotus Notes, users can collaborate and share ideas with team members on joint projects, participate in group discussions, and create document libraries. Rather than waiting for an e-mail message to come to you, with Notes you have the power to find the information just when you need it.

The greatest value of Notes is realized when it is used to create custom business applications that coordinate everyday business processes from start to finish to achieve results — like improving customer service, making your sales force more effective, and managing your most valuable asset, your people.

All users exploit the power of Notes as a central access point for all corporate information, including desktop documents, group discussions, e-mail messages, relational data, Web pages and news feeds. What's more, mobile Notes users can "take their desktop" with them — transforming airports, hotels and cars into workspaces complete with up-to-the-minute information.

Lotus Notes and Lotus Organizer are registered trademarks and Notes, LotusScript, NotesPump, Notes HiTest, Network Notes, Notes Mail, Notes Desktop and InterNotes are trademarks of Lotus Development Corporation. cc:Mail is a trademark of cc:Mail, Inc., a wholly owned subsidiary of Lotus Development. IBM, DB2, OS/2 and AIX are registered trademarks of International Business Machines Corp. Oracle is a registered trademark of Oracle Corporation. Sybase and Replication Server are registered trademarks of Sybase, Inc. DataLink is a trademark of Brainstorm Technologies, Inc. Replic-Action is a trademark of Casahl Technologies, Inc. ZMERGE is a trademark of Granite Software, Inc. EDA/SQL is a trademark of Information Builders. InfoPump is a trademark of Trinzic, Inc. Visual Basic and Windows are registered trademarks and Windows NT is a trademark of Microsoft Corporation. SQLWindows is a registered trademark of Gupta Corporation. New Era is a trademark of Informix Software, Inc. PowerBuilder is a reg istered trademark and PowerSoft is a trademark of PowerSoft Corporation. Macintosh and AppleTalk are registered trademarks of Apple Computer, Inc. UNIX is a registered trademark of X/Open Company Limited. NetWare is a registered trademark of Novell, Inc. Solaris is a registered trademark of Sun Microsystems, Inc. HP-UX is a trademark of Hewlett-Packard Corporation. VINES is a registered trademark of Banyan Systems Incorporated. AT&T is a registered trademark of American Telephone & Telegraph Company.

2.7.1 Lotus Domino R5 Application Server

Key Features and Benefits

- **Integration with enterprise systems.** Leverage current information assets with built-in connection services for live access to relational databases, transaction systems and ERP applications.
- **Optimized for collaboration.** Provides comprehensive application services like workflow and messaging, so you can easily build and manage integrated, collaborative solutions.
- **Simplified deployment and maintenance.** Integrated development tools, standards support and unmatched server-to-server replication simplify rollout, maintenance and rollback of applications.
- **Open for more choices.** Use your favorite HTML authoring tools, Java IDEs and scripting tools to create Domino applications. Use Microsoft IIS as the HTTP engine for Domino.

The Power to Connect People -- Easily, Securely, Reliably

The Lotus Domino Application Server is an open, secure platform optimized to support rapid delivery of collaborative Web applications that integrate your enterprise systems with dynamic business processes.

Increase the Return on Current Investments Domino Application Server enables you to further leverage current Web investments. Domino Enterprise Connection Services (DECS) provides rapid connectivity to enterprise data. CORBA/IIOP support lets you integrate Domino with your applications architecture. Support for Microsoft ITS brings Domino's rich application services to NT Web environments.

Create Higher-Value Applications A comprehensive development environment, the Domino Application Server lets you move beyond static Web sites -- to create high-value business solutions that include workflow, content management and highly flexible security. No platform makes it easier to create self-service applications like e-commerce and customer care, and connect them to back-end systems.

The Domino Server Family The Domino Server Family is an integrated messaging and Web application software platform for growing companies that need to improve customer responsiveness and streamline business processes. You can rely on the top-rated, global service and support of Lotus, IBM, and our worldwide network of Business Partners to help you maximize the return on your Domino infrastructure investment.

2.7.2 The Domino Application Server is a world-class Web application server.

- **CORBA/IIOP support.** Extend Domino application services to Web clients, for integration with your existing applications architecture. Serve Lotus Notes clients and Web browsers with the same applications.

- **Flexible, pervasive security.** Personalize access to data and applications based on individual and group roles. Extend Domino security to HTML files and other data, for pervasive security no matter how or where Web content is stored.
- **Enhanced HTTP stack.** The Domino R5 HTTP engine delivers outstanding performance and Java Servlet support.
- **Integration with Microsoft IIS.** Use IIS as the HTTP engine for Domino, to dramatically enhance IIS security and bring Domino's rich Web application services to your NT-based Web environment.

2.7.3 The Domino Application Server offers the industry's most comprehensive array of services.

- **The most flexible security model.** Integrated X.509 support lets you register new users with Notes and/or X.509 certificates. S/MIME support ensures message integrity for all client types. SSL V3 for HOP and LDAP clients. Authentication via trusted third-party directories reduces complexity and duplication of information.
- **An enterprise-scale, LDAP directory.** Support a multi-enterprise infrastructure of any size. Integrate with other directories via full support for LDAP V3, the open standard for directory access. Extensible schema allow you to store any information you choose. Synchronizes user accounts with the Windows NT directory.

- **The world's best workflow.** Easily define processes to route and track documents, to coordinate activities both within and beyond your organization.
- **Enhanced search services.** Provide domain-wide searching across all your Domino applications and the file system, built-in search security, universal filters and more.
- **An integrated development environment.** Domino Designer is optimized to work with Domino, and features a complete set of visual tools for rapid development and deployment of secure, e-business solutions. Support your favorite tools for HTML authoring, Java development, and scripting.

2.7.4 Domino Application Server includes Domino Enterprise Connection Services (DECS), for live access to enterprise systems.

- **Comprehensive connectivity.** DECS supports a wide range of enterprise systems, including DB2, Oracle, Sybase, ODBC, EDA/SQL, SAP, PeopleSoft, JD Edwards, Oracle Applications, MQ Series, CICS, and more. (Connectors for relational databases are included with Domino; connectors for ERP applications and transaction processing monitors are sold separately.)
- **The most efficient integration available.** Provide access or update enterprise data from your Web applications in real-time, via persistent, parallel, pooled connections.

- **Your choice of development options.** Connect to enterprise data non-programmatically via the easy-to-use DECS interface, or programmatically from Java or LotusScript.

2.7.5 The Domino Application Server delivers unmatched reliability and manageability.

- **Transactional logging for Domino databases.** The industry standard for reliable data storage ensures complete data integrity for updates and facilitates incremental database backup and fast restart after system failures.
- **Backup support.** APIs allow tight integration with third-party backup tools on all Domino platforms, including NT, UNIX, AS/400 and S/390.
- **High availability services.** Provide online indexing and database compaction, fast server restart and more.
- **Remote server management options.** Improve convenience for administrators and provide consistent IT support for field offices with remote server management via the Domino Administrator, optimized administrative tools, Web-based administration, batch console commands and more.
- **Centralized control of Notes desktops.** Organizations that use the powerful Lotus Notes client for mail and applications can centrally configure desktop settings like home server and UI preferences.

- **Mail Server capabilities.** The Domino Application Server also delivers powerful administration and the unmatched Internet messaging functionality found in the Domino Mail Server such as e-mail, calendaring and group scheduling, bulletin board and newsgroups.

Supported operating systems:

Microsoft Windows NT 4.0 (Intel, Alpha), IBM AIX 4.3.1, HP-UX 11.0, Sun Solaris 2.6 (SPARC and Intel), IBM OS/2 Warp Server 4, IBM AS/400 V4R2 or later, IBM S/390 V2R6 or later.

Domino Application Server is licensed for deployment on systems with one to four CPUs.

For more information:

To find out more about the Domino Application Server and other Domino server products, visit the Lotus Web site at http://www.lotus.com/dominoapplicationserver

2.8 ISO Master TM

2.8.1 Company profile

Master Info Consulting Co.,Ltd. was found in August, 19 The founder of this company; Khun Vanchai Limpithip whose previous career was the Quality Management Representative in Caltex Oil (Thailand) Ltd. After successful years of implementing ISO 9000 Quality System in CALTEX he retired from the company to run the ***Master Info***

Consulting Co.,Ltd. with his partner; Khun Vorasit Vinkomin who is now the Managing Director of ***Business Solutions Provider Co.,Ltd.***

Master Info Consulting Co.,Ltd., ' s head office is situated at 498 Soi Petchkasem 81, Petchkasem Rd., Nongkaem, Bangkok 10160, **Tel: 812-1712, 420-1041, Fax: 812-1712.**

E-mail; vanchail@loxinfo.co.th

or ***Business Solutions Provider Co., Ltd***

7/129 Central PinKlao Office Tower, 7 Flr. Baromrajchonnee Rd. Bangkok 10700,

Tel: 884-9185-6, Fax: 884-9145

E-mail; vorasit@bspc.co.th

Its business is to develop the *Electronic Documentation & Workflow Management* Application which runs on Lotus Notes. This application basically and fully supports the requirement to manage all types of documents in ISO 9000, ISO 14000, ISO 18000, and ISO TC Guide25. Also the company will provide *consultancy to any organizations that require implementing of ISO 9000 Quality System.*

The Electronic Documentation & Workflow Management is named **ISO Master TM;** its full features are described in the next pages. **ISO Master TM** is the quality product developed by combining two successful experiences together; the ten years' experience of ISO 9000 quality system with the Certified Lotus Notes Principle (CLP) & Certified Lotus Notes Instructor (CLI) resulting the outcome of;

- Application reliability
- Meet requirements of ISO 9000, ISO 14000, ISO 18000 and any other type of documents
- Support of all technical and Application Training

- Extending and/or modification be enable
- Economic Application Package price
- User-friendly

2.8.2 The Support

ISO Master TM is locally developed. That is the reason why you will have full support, of any technical problems that may be arising, by our developing team. Also we shall facilitate, modify, and design any other processes according to the requirements in your organization, if you request.

2.8.3 Document & Data Control Features and Benefits

Features

- All document types required by ISO 9000
- Pre-Defined Document Format for ISO 9000 requirements
- Electronic Workflow capability with Electronic Signature
- Programmable workflow Management down to document type and area
- Security control down to document level
- Document Status Tracking
- Automatic Notification to Document Readers and all concerns
- Automatic remove previous document after new revision is effective
- Change Request record tracing from the current document
- Document Master List for easy viewing by views;

- *Change Request document*
- *In-progress document*
- *Future Use Document*
- *Controlled Document*
- *Obsolete Document*

- A powerful Full Text Search (can search every text in any field in a database include file attachment)
- Distribution Control via Local Area Network or Intranet or Internet
- Very compact storage size
- Support Multiple user
- Other Windows application, such as Visio, Microsoft Excel, MS Word, ... etc.
- Multimedia information

Benefit

- Speed of the document approval process (Using Electronic Signature is accepted by Certified Body around the world)
- Easy Document Management and Maintenance
- Low cost of Document Distribution via Workstation, Replication, Intranet, Internet
- Low printing cost
- Compact Storage size (because electronic document can be archived in CDs, Tape or Hard-Disk)
- Fast document retrieve

- *Via View index for example, Index by .... etc.*
- *Via Full Text Search (search for any word, combination in any of the document field in Database)*
- *Referring between Documents can be done easily via Document Link (for example, Current Document link to Revision History Record and further to Change Request)*

- Alert and Notify can be done automatically via the use of Automatic Agent
- Better Security
- *Authentication*
  - *Database Access Control Levels*
  - *View Access Control*
  - *Document Access Control (Document Read access)*
  - *Document Section Access Control*
  - *Field Encryption for a very secure document*

2.8.4 Internal Quality Audit Features and Benefits

Features

- General IQA Checklist format (can be pre-written to suite the need of an organization)
- On-line IQA Plan
- Automatic Notification to all involved personnel
- On-line Posting Discrepancy Record
- Link to Open CAR by clicking a button

- On-line link to PAR/Management Review Agenda
- Multiple viewing with easy record retrievable for Audit Checklist, IQA Plan, and Discrepancy Record view.
- Documents can be sorted by;
    - *Checklist*
    - *Discrepancy Record*
    - *IQA Plan*
    - *IQA Completed*
    - *By Status*
    - *And many many more... as required by your organization.*

Benefit

- All areas can read the IQA Plan via network on-line, making communication more effective
- All areas concerned will be notified of audit schedules and can confirm back to Auditor via network on-line.
- Save manpower of conducting the Internal Quality Audit
- No hard-copied records required

Effective record retention and easy retrievable records will satisfy the third party auditor.

2.8.5 Corrective Action Request Features and Benefits

Features

- Open CAR On-line
- Send to responsible personnel for investigating the root cause via network on-line.
- Record all investigation, root cause analysis, corrective action in single CAR form format.
- CAR record, which can link to Management Review and/or can be on-line reviewed by the Management.
- Electronic sign by the CAR record
- CAR record retention in software
- Easy retrievable via navigator view;
    - *By Date Open/Close*
    - *By Area audited*
    - *By Auditor Name*
    - *By CAR Number*
    - *By Status*
    - *And many more as required by your organization.*

Benefit

- CAR process is done on network, making it more effective and reducing operating cost.

- Responsible area/personnel can easily record any investigation, root cause analysis, and corrective action on-line without issuing any hard-copied paper.
- Clarified and effective communication among the areas concerned.
- Management Review can be conducted on-line by reviewing CAR records.
- The management can easily electronic sign closing out the CAR.

Low cost CAR record retention, no hard-copies required.

Effective record retention and easy retrievable records will satisfy the third party auditor.

2.8.6 Management Review Features and Benefits

Features

- On-line Management Review agenda issued to all personnel via network.
- On-line notify and confirm of Management Review schedule date.
- On-line record of the meeting minutes in Management Review form.
- On-line meeting minutes and assignment of actions to all concerned via network.
- Electronic sign to close out the corrective action.
- Any meeting material such as charts, statistics, tables, be integrated or link to be reviewed.
- Management Review record views at all status during process workflow;
    - *MR Agenda*
    - *MR Minutes*
    - *MR Actions*

Benefit

- Management Review Meeting agenda can be effectively communicated to all areas via network.
- Meeting minutes can be recorded on-line during the meeting.
- Easy to follow-up and track the corrective action in accordance with the meeting minutes.
- The management can review any statistics, measurements, proposal, and information on-line.
- Operating cost is reduced because no hard-copy and transparent presentation are required.

Effective record retention and easy retrievable records will satisfy the third party auditor.

2.8.7 Training Features and Benefits

Features

- On-line Training Plan
- Providing List of Qualified Instructor
- On-line notification, confirmed, conduct training, evaluation, completed status
- Keeping evaluation record in software file
- All Training records seen and easy retrieved via navigator view;
    - *o By Course List*

- *By Evaluation Form*
- *By Instructor Information*
- *By Training Plan*

All documents/records be electronic signed

Benefit

- Training Course can be easily pre-defined, making it easier to conduct the training.
- Training Plan is pre-defined, making it the effective communication to all areas concerned.
- Pre-define the qualified instructor to each course/job title.
- Pre-define Evaluation Criteria to run the individual test/training result.
- Low cost to keep all Training records in software media instead of hard-copied records.
- Training Record retention and retrieving made easy in a large organization.
- Easy retrieving of all training records for the auditor to review.

Chapter 3 Methodology

3.1 Objectives

3.1.1 Study and survey the performance in feature software of the most famous Thai ISO 9000 commercial software package (ISO Master).

3.1.2 Survey the customer satisfaction with that commercial software package (ISO Master).

3.1.3 Discuss and guide to the future software for ISO 9000 system in Thailand.

3.2 Scope

This study scope and limitation is

3.2.1 The survey of performance and satisfaction of the companies that used ISO Master data and some interview is used for future software discussion.

3.2.2 The software of this study focuses on commercial software package that aims to help the small and medium companies in Thailand to use this tool to maintain and continually improve this quality system.

3.3.3 The most famous software using for ISO 9000 system is ISO MASTER, because only one software package is used in Thailand.

3.3.4 The target group of companies is the group of the ISO 9000 certified company in Thailand, especially 36 companies that used ISO MASTER for ISO 9000.

3.3 Methodology

The definition of the utilization can be defined into 2 parts as follows:

Part one, in performance of feature on software to cover ISO 9000 in classification by each module of software such as document control, management review, corrective action, training and internal audit.

Part two, in the view of customer satisfaction of using this software in speed, quality, flexibility and cost saving on operation.

The study of this topic is classified into 3 parts

33.1 Part one Thai commercial software package in Thailand and ISO 9001 Version 2000

By documentation study and searching, researchers will find Thai commercial software package in Thailand. They then study The ISO 9001 Version 2000. So The matching between ISO 9000 system and feature of software is explicated. After researchers select the most famous Thai commercial software package for ISO 9000 the second part will provide.

3.3.2 Part two : The performance and satisfaction of the ISO 9000 package

After selecting the most famous Thai software package, then this process is as Follows:

1. Study the Existing software using to enhance the performance of

maintaining the Quality management system (ISO 9000) for the companies in Thailand.

2. Design the questionnaires to gather information of the performance and satisfaction of the selecting software that those companies used in Thailand via email ,mail ,facsimile and call for interview.
3. Analyze the data and then discuss the existing software to improve Quality Management System in the performance viewpoint.
4. Comment and suggest the future software for this objective for companies in Thailand.

The criteria for designing the questionnaires are as follows

3.3.2.1 Criteria for evaluation the software performance.

Before we discuss specific approaches to acquiring systems, let us consider in more detail what constitutes desirable outcomes of the acquisition process. The most prominent considerations are:

1. **On-time.** Completion and implementation of the system on or before the scheduled target date.

2. **On-budget.** The system cost is equal to or less than the budget.

3. **Full functionality.** The system has all the features in the original specifications.

These outcomes are very desirable, especially since fewer than half of all systems projects achieve all three. However, it is possible to succeed in each of these criteria but still have a system that does not increase the effectiveness of the organization. Therefore, the following outcomes are also important:

4. User acceptance. Some systems perform poorly or even fail solely because of resistance from the users. One reason for resistance is a poor user interface that makes a system difficult to learn or use. Perceptions that the system shifts power from one part of the organization to another, or increase management control over employees, can also lead to resistance.

5. Favorable cost-to-benefits ratio. A system may have all the specified functionality but still not help the organization because actual benefits and / or operating costs differ substantially from the initial estimates. This unfavorable outcome is becoming more common as organizations exhaust the possibilities for automation projects that replace manual labor with computer functionality. Decision makers must increasingly use intangible benefits, which are much harder to predict, to justify new systems.

6. Low maintenance. Up to 80 percent of the operational ISD budget now goes for maintenance of existing systems. This implies that a more expensive system, which is easier to maintain or has greater functionality, could be more beneficial to an organization than one that is difficult to update or needs subsequent enhancements in its functionality.

7. **Scalability.** Processing volumes can increase as usage levels expand and as organisations grow. It may therefore be necessary to migrate a system to another hardware platform with greater capabilities. If the original system is based on software that is portable to different platforms, for example, a common database management system, the migration should be cheaper and less difficult.

8. **Integration with other systems.** A system may achieve all its own design objectives but not coordinate well with other systems in an organization. For example, some of its data may overlap files in other locations. The end result would be less organizational cost savings than available through more integrated systems.

9. **Minimal negative cross impacts.** A new system may be successful by itself but create major problems for an organization in other areas. For example, a new system could put unacceptably large demands on limited computing resources and result in unacceptable delays on other systems during peak demand.

10. **Reusability.** Ideally, some of the more general codes developed for the new system would be reusable. If so, it could save money in future systems development projects.

SELECTING COMMERCIAL SOFTWARE PACKAGES. The criteria listed above can be used to select specific software packages, either for development and I or applications. Other criteria that can be used are:

1. Cost and financial terms
2. Upgraded policy and cost
3. Vendor's reputation and availability for help
4. Vendor's success stories (visit their Web site, contact clients)
5. System flexibility
6. Ease of Internet interface
7. Availability and quality of documentation
8. Necessary hardware and networking resources
9. Required training (check if provided by vendor)
10. Security
11. Learning (speed of) for developers and users
12. Graphical presentation
13. Data handling
14. Environment and hardware

3.3.2.2 Criteria for Evaluating processes within the quality management system

1. **When evaluating quality management systems (QMS), there are four basic questions that should be asked in relation to every process being evaluated.**

a) Is the process identified and appropriately defined?

b) Are responsibilities assigned?

c) Are there procedures implemented and maintained?

d) Is the process effective in achieving the required results?

The collective answers to the above questions can determine the result of the evaluation. Evaluation of a QMS can vary in scope and encompass a range of activities, such as auditing and reviewing the QMS, and self-assessments.

2. <u>Process Orientation Requirements:</u>

- Identify processes required (to achieve scope)
- Determine sequence and interaction
- Determine control criteria and methods
- Ensure availability of process information
- Measure, monitor and analyze processes
- Implement actions to achieve planned results.

3. <u>Managing processes:</u>

- Define processes needed to achieve desired results
- Identify and measure inputs and outputs
- Identify interfaces (planning, QA, MGMT) – Who is responsible to collect, analyze and use data – how to communicate
- Evaluate risk, consequence and impact on customers

- Establish responsibility, authority and accountability for managing the process
- Consider all resources necessary to achieve the desired result.

❖ **Two types of processes –**

4. **<u>Realization processes</u>** – Primary (Direct – value added)
    - How are these processes controlled from contract review up to and including delivery?
    - Examples: contract review, design, purchasing, production

➢ **<u>Support processes</u>** – Management (Indirect – Non-value added)
    - How is the system maintained and how is knowledge about the functioning of the system converted into improvements?
        - Examples: managing information, training, financial related activities, infrastructure and service maintenance, and marketing.

5. **After process identifications are complete (which makes visible the inputs and outputs that flow between departments) can be used to:**
    - Understand how work currently gets done (how the organization works as a system)
    - Identify "disconnects" in the organizational wiring
    - Eliminate disconnects
    - Evaluate alternative ways to group people

6. **<u>Cycle Time Concepts – Three levels for any process:</u>**

- Baseline (current run rate)
- Process capability (what can reasonably be expected without adding resources)
- Theoretical (sum of value-added steps only)

7. Key questions:

- What is keeping us from being closer to theoretical?
- What can be done to get closer?

8. Process improvement questions:

- Why are we doing this?
- Can this step be eliminated?
- Can this step be combined with others?
- Can this step be simplified?
- Can this step be done in parallel with other steps?

9. Main ingredients for improvement:

- Have will to change – LEADERSHIP
- Know what to say – MANAGEMENT SYSTEMS
- Know how to do it – TRAINING
- DO IT – and improve (continuously and have a well-defined PROCESS for implementation towards success

10. Key Process Review Details

- Specify process type – Realization or Support
- Identify Inputs – what is received in order to perform activities
    - Processed Material (raw materials, components, supplies, etc...)
    - Services (calibration, inspection, cleaning, etc...)
    - Hardware/equipment (major units only)
    - Software Controls (any system not run manually – temp controllers, timing systems, etc...)
- Detail Activities – what is done, step-by-step
    - Processed Material
    - Services
    - Hardware/equipment
    - Software Controls
- Identify Outputs – what the end product is
    - Processed Material
    - Services
    - Hardware/equipment
    - Software Controls
- Goals – the final result(s) for this process
- Objectives – of each goal
- Metrics – what measuring system is in place to ensure the goals are achieved
- Link documents (Corp Specs, CWIs, SOPs and Forms) where they are used

For customer of this topic questionnaire, is see Appendix A.

3.3.2.3 Sampling design

The only one Thai commercial software package is valid in Thailand and their customers are 36 companies (Appendix B : Site reference list).

By using simple random sampling formula

Finite population $n = \dfrac{Np_q}{\dfrac{(N-1)\,B^2 + P_q}{Z^2}}$

n = Sample size

N = Population size

6 = Variance of population

B = Error =10 %

Z = Z score by confidence level 95%

$Z_{0.1} = 1.65$

Probability of population

1—P

N = 36 B = 10%

P = 0.5 Z = 1.65

q = 0.5 a = 90%

$$\frac{36(0.5) \times (0.5)}{\dfrac{(36-1)\,(0.1)^2 + (0.5)\,(0.5)}{(1.65)^2}}$$

Calculation Sample size = 23.77

After we have sampling size and questionnaire, we send the questionnaire via email ,mail ,call for information.

3.3.2.4 Questionnaire design

There are three parts of questionnaire; the first part is for gathering general information, the second part is for gathering factors score of performance and customer satisfaction of this software and the last pert is for collecting client attitude and opinion for feature developing software for ISO 9000.

The list of questionnaire is from the 5 features of the software grouping such as Training, document control, corrective action, management review and internal audit Feature. Then we considered their features' benefit (2.8.3 to 2.8.7 in chapter 2) and consider the characteristic for good software and ISO 9000 system that is shown in chapter 3 topic 3.3.2.1 and 3.3.3.2, and design the questionnaire as follows:

3.3.2.5 List of questionnaire

1. Speed of documentation approval by electronic signature
2. Reduction in the quantity of paper in workforce
3. Security in confidentially document
4. Speed accuracy of data searching
5. Ease to update data and information
6. Effectiveness and efficiency of communication

7. Ease to internal audit conclusion
8. Ease to retrieve internal audit data
9. Time saving for conclusion the result of internal audit
10. Reduce in manpower Internal Quality Audit
11. Reduction in failure and error for new employees
12. Ease to check system error
13. Fast and accurate data analysis and collecting
14. Reduction in process of approval
15. Efficiency of meeting agenda flows and covers company wide
16. Help for minute meeting conduct
17. Ease to correct the minute meeting
18. Fast convenience to review data
19. Help for training needs
20. Fast for training schedule dispatching
21. Convenience and saving area for training document
22. Easy learning for development and users
23. Efficiency of data management
24. Better for follow up by management review
25. Good connecting of management system
26. Ease for summary of data and presentation
27. Flexibility system
28. Speed of learning curve of users
29. Better quality of document

30. Better communication

After we received the results from the customers, we group the list by using the indicators that represent the customers' feeling as

1.) Quality: it means that this software is good at quality viewpoint.

2.) Flexibility: it means that customers are satisfied with flexibility.

3.) Cost: it means that this software is reasonable cost.

4.) Speed: it means that this software is helped for speed of work.

The item numbers of questionnaire shown in there indicators are as follows:

1.) Topic number 3, 11, 12, 24, 29 and 30 represent quality of the software.

2.) Topic number 5, 6, 15, 25 and 27 represent the flexibility of this software.

3.) Topic number 2, 10, 14, 18 and 21 represent the cost of this software.

4.) Topic number 1, 4, 7, 8, 9, 13, 16, 17,19, 20, 22, 23, 26 and 28 represent the speed of the software.

Moreover, we grouped the questionnaires by features of software module to know which features the customers prefer as follows:

1.) Topic number of questionnaires 3, 6, 11, 15, 16, 17, 18, 24, 25, 26, 27 and 30 are in the management review module feature.

2.) Topic number of questionnaires 19, 20, 21, 22 and 28 are in the training module feature.

3.) Topic number of questionnaires 1, 2, 4, 5, 23 and 29 are in the document and date control feature.

4.) Topic number of questionnaires 7, 8, 9 and 10 are in the Internal audit feature.

5.) Topic number of questionnaires 12, 13, and 14 are in the corrective action feature module.

The evaluation point is classified as

1.) The average score between 4.01 to 5.00 means the customers are fully satisfied with the software and ready to use software to help ISO 9000 system in company.

2.) The average score between 3.01 to 4.00 means the customers are satisfied with the software.

3.) The average score between 2.01 to 3.00 means the customers are neutral. They use the software in their job and are not fully satisfied. If there are any option or alternatives, they suppose to change to other solutions.

4.) The average score between 1.01 to 2.00 means that the customers are dissatisfied with their software.

5.) The average score between 0.00 to 1.00 means that the customers are highly dissatisfied with their software any more.

After we receive that result score from questionnaires, we average it by grouping into indicators and features.

The score will be presented the satisfaction of customers in performance viewpoint and feather viewpoint of this software.

3.3.3 Part three: ISO 9000 certified companies that still do not use software

To know the reason why the commercial software implementing in the major part of the companies that received ISO 9000 certification, we interview by phone and fax to fax and gather the information.

So in brief the methodology of this topics study is as follows:

1. Determine the problem statement, project objectives.
2. Study the Software using for ISO 9000 in Thailand.
3. Study the evaluation of the Quality management system (.ISO 9000).
4. Detailed study of the selected software that is well-known.
5. Collect the list of software users.
6. Make sampling design.
7. Design questionnaires.
8. Make post office arrangements.
9. Prepare test questions.
10. Review questionnaires.
11. Approve questionnaires.
12. Follow up answers.
13. Collect data & prepare.
14. Analyze data & interpret.

15 Report the project.

16 Make project conclusion & recommendations.

17 Present the project.

Chapter 4 Finding

4.1 Finding

According to three parts of study, researchers found that

4.1.1 Part one: Thai commercial software package in Thailand and ISO 9001 Version 2000

There are only 5 modules of ISO Master that support ISO 9001 Version 2000 system as follows:

1. Document & Data control
2. Internal Quality Audit
3. Corrective Action Request
4. Management Review
5. Training

The above modules supports ISO 9001 Version 2000 only sub systems that commonly support the sub systems in ISO 9001 and ISO 14001 (Environmental Systems). So this software does not cover all of the sub system in ISO 9000 that are called infrastructure of the system because the vendor would like to sell this package not only for ISO 9000 but also for ISO 14001 and OHSA 18000.

All of ISO series consists of these sub systems as infrastructure.

The famous Thai made commercial software is ISO Master, the details of which are in Chapter 2 and Appendix C.

The common benefit of this ISO Master software is

1. Easy for retrievable data and record, and follow-up
2. Done on network, making it more effective and reducing operating cost.
3. Clarified and effective communication among the areas concerned.
4. Cost saving for document and keeping area.
5. On-line link to management review and each sub system, creating better communication and fast decision.
6. Reduction in the redundant process of system,

And **the limitation** of this software is

1. Non-coverage of all areas of ISO 9000 system, as mentioned that this package supports only common the sub system of Quality management system.
2. For continual improvement, the heart of ISO 9000, it is not quite sure and flexibility of software for applicators is fully supported by this software.
3. To interface with the complexity companies' process in the large scale enterprise or big size firm is still doubtful.
4. Other area of ISO 9000 system such as customer survey and review and history is not included in this package.

The difficulty of this software package implementing is as follows:

1) Upgrade of software infrastructure (Lotus Notes) is often minor changed so the client is not confident if this software package is update for software infrastructure upgrade (version changed).

2) Skill users for infrastructure software in small and medium size companies is not enough for implementation of this software.

4.1.2 Part two: The performance and satisfaction of the ISO 9000 software package

The customers that use this software is satisfaction in high level (level up) Feed back 85 percent from sampling size 20 and the two companies used software but not successful two of this companies are big scale firm because of complexity process, number of users and mismatching to existing system. (see table 4-1 Questionnaire result).

Table 4-1, Questionnaire result

Source : Survey by mail ,email and call

No.	Factors that have impact on customer satisfaction of software to help ISO 9000	Average
1.	Speed of documentation approval by electronic signature	4.88
2.	Reduction in the quantity of paper in workforce	4.82
3.	Security in confidentially document	4.41
4.	Speed of accuracy of data searching	4.18
5.	Ease to update data and information	4.24
6.	Effectiveness and efficiency of communication	4.18
7.	Ease to internal audit conclusion	4.06
8.	Ease to retrieve internal audit data	3.35
9.	Time saving for conclusion the result of internal audit	3.76
10.	Man power reduction for Internal Quality Audit	4.12

Table 4-1, Questionnaire result

Source : Survey by mail ,email and call

No.	Factors that have impact on customer satisfaction of software to help ISO 9000	Average
11.	Reduction in failure and error for new employee	4.12
12.	Ease to check system error	4.14
13.	Fast and accurate data analysis and collecting	4.06
14.	Reduction in process of approval	4.88
15.	Efficiency of meeting agenda flow and cover company wide	4.24
16.	Help for minute meeting conduct	4.35
17.	Ease to correct the minute meeting	4.06
18.	Fast convenience , to review data	4.29
19.	Help for training needs	4.00
20.	Fast for training schedule dispatching	4.12
21.	Convenience and saving area for training document	4.88
22.	Easy learning for develop and users	3.18
23.	Efficiency of data management	429
24.	Better for the follow-up by management review	4.35
25.	Good connecting of management system	4.06
26.	Ease for summary of data and presentation	4.24
27.	Flexibility system	4.12
28.	Speed of learning curve of users	3.33
29.	Better quality of document	4.29
30.	Better communication	4.59
	Total average	**4.26**

Degree of satisfaction 1 = not at all 2 = less 3 = medium 4 = good 5 = excellent

The interpretation of the average score that is received from the customers are as follows:

Part one, in term of performance of feature on this software we find the following:

1. In view of each module of this software, the customers are fully satisfied with the document control (4.45 points), on corrective action (4.36 points) and management review (4.25 points).
2. The customers are not so much satisfied with training module and internal audit (3.90 points and 3.82 points).

Part two, in terms of customers' satisfaction on speed, quality, flexibility and cost saving we find the following:

1. Total view of customers is very much satisfaction of this software, 4.26 point.
2. In terms of cost saving on operation, the customers are fully satisfied with this software on this function (4.59 points).
3. In view of quality the customers are satisfied, (3.99 points).
4. In view of speed of the software to help manage ISO 9000 system the satisfaction is high (4.3 points).
5. The minimum score of this survey is 3.16 points, on the difficulty of learning for development and users.
6. The maximum score of this survey is on the convenience and saving area for training document, Speed of documentation approval by electronic signature and reduction in the process of approval (4.88 points). So we can say that customers are satisfied with this software in these features.

The limitation of this software from questionnaire survey is as follows:

1) Not suitable for big scale firms
2) Inconvenience for upgrade software and infrastructure
3) Not suitable for complicated processes in some companies

The benefit of this software from questionnaire survey is as follow;

1) Cost saving of document, time and manpower.
2) Speed of communication and operation.
3) Online communication, reducing internal processes.

4.1.3 Part three: ISO 9000 certified companies that still do not use software

The difficulties from 5 companies interviewed about the reason, why they do not use software to help the ISO 9000 in their companies are as follows:

1) No budgeting
2) Lack of people to take care this software
3) Not sure to upgrade the software
4) No coverage of all areas of ISO 9000
5) Software not fit to company culture.

The feature software that should be developed for ISO 9000 from this study is as follows:

1) The coverage of all areas of ISO 9000 system needed to utilize the technology tool to cover the maintenance and continual improvement of ISO 9000 system must be more

considered by software developers to gain more advantages and utilization by using the software.

2) System flexibility and upgrade of software is needed for the software is always changed.

3) To cover the complexity of activities of the firm is more and more required from client , and customize to customers is concerned, although this software is commercial software package.

The summary of finding as the objective of this project is to study the most famous Thai ISO 9000 commercial software package is ISO Master. There are 36 ISO 9000 certified companies that use this software to maintain the ISO 9000 system. From the study the software does not cover all areas of the whole ISO 9000 system. It consists of only 5 modules and difficulties for the large scale companies.

For the survey of the customer satisfaction of this ISO Master, the result shows the high level of satisfaction on this ISO 9000 package by ISO 9000 certified companies that use this software. The study of the difficulties of this is not suitable for large scale companies and upgrade ability of this software.

For the feature of Thai software for ISO 9000, the key features to be added on the existing one are the upgrade ability, the coverage of ISO 9000 system and support of the complexity of activity and customization.

Chapter 5 Conclusion and recommendation for further project

5.1 Conclusion and recommendations

The conclusion of this project is to answer the problem statement and achieve the purpose and objective setting. (Discuss in Chapter 4 finding)

There is only one Thai-made commercial software package to maintain ISO 9000 for ISO 9000 certified companies in Thailand. In view of the software functional performance feature, the existing software users are still satisfied with the features of this software. There are document and date control, internal audit, Corrective action request, Management review feature and Training features in this software. But, from the desk study of the author, this software feature does not cover to ISO 9000 version 2000 compliance.

In the view of customer satisfaction on software performance benefit, the survey result from questionnaires shows that the customers that use this software are satisfied with this software performance in terms of speed, quality, and flexibility and cost saving. And the small number of ISO 9000 certified companies uses the software as a technology tool to help and overcome their difficulties on implementation and maintaining the quality system compared to the big number of ISO 9000 certified companies which do not use technology tool (software) to help their quality system management. This shows that a big room to develop the software by the Thai firm to fill the gap of demand of this customer area needs full support from Thai government. To enhance Thai software house

to develop Thai-made software to fill the gap of market in Thailand in the future. The trend of this special software package for special purpose in terms of niche market is high in this ISO 9000 case. It is one example. So the development of software itself, software house and this shows a big room to develop the software by Thai firm to fill the gap of demand of this customer area that needs full support from Thai government. Thai users are needed to strengthen this business sector to improve Thailand's trade balance and economy status. The increase in software developers and software providers will make the price of software decrease. The decrease in software price will stimulate and encourage more and more users to use the technology tool (software) to gain more competitive advantages on their management.

The difficulties from 5 companies interviewed about the reason why they do not use software are as follows:

1.) No budgeting.

2.) Lack of people to take care this software.

3.) Not sure to upgrade the software.

4.) No coverage of all areas of ISO 9000.

5.) Software not fit to company culture.

The comments or suggestions for the future software feature for ISO 9000 certified companies in Thailand are as follows:

1.) Cover ISO 9000 requirement.

2.) The software must be flexible.

3.) The software must be customization and users friendly.

4.) There are upgrade policy and cost reasonable of the software.

5.) The ease of learning for developers and users.

6.) The ease of Internet interface is considerable by customers.

7.) The customer's still concerned about the vendor's reputation and availability for help.

The total picture of Thai-industries will be better than the present by leveling up the software standard, encouraging the new software developers, setting the R&D and development institution for software developers. To hold the content and fairness for software developers' full support from Thai government is needed.

5.2 Recommendations for further study

1) Why did ISO 9000 certified companies not use the commercial software packages to help their quality management system ISO 9000? This project did not cover and accurately evaluate the reasons why customers did not use this software due to limitation of time.

2) The trend study of software itself when ISO 9000 system is upgraded in every 6 years in terms of system upgrade is recommended to study.

3) The feasibility study in terms of business purpose for the new ISO 9000 commercial software package must be done before making decisions to develop the new software for ISO 9000.

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APPENDIX A

คณะ สตร์และเทคโนโลยี
มหาวิทยาลัยอัสสัมชัญ

"การสำรวจความพึงพอใจของลูกค้าในการนำ Software มาช่วยจัดระบบคุณภาพ **(ISO** 9000)

เรียน Quality Management Representative (QMR)
ขอความร่วมมือในการตอบแบบสอบถาม
แบบสอ11ถาม

ข้าพเจ้านางสาววุฒิธร มหัทธนวงศ์วาน ซึ่งเป็นนักศึกษาระดับปริญญาโท หลักสูตรการจัดการเทคโนโลยีมหาบัณฑิต (Technology Management) คณะวิทยาศาสตร์และเทคโนโลยี 3411111 Ellลัยอัสสัมชัญ แบบสอบถามนี้จัดทำขึ้นเพื่อเก็บรวบรวมข้อมูลความพึงพอใจ กค้าในก รใช้ Software ซึ่งนำมาช่วยจัดการคุณภาพ (ISO 9000) ในประเทศไทย โดยศึกษาจากบริษัทที่ใช้ Software ที่ผลิตในประเทศไทย

ดังนั้น ข้อมูลต่างๆที่ตรงกับความคิดเห็นของท่าน จะเป็นสิ่งที่ช่วยให้การศึกษาครั้งนี้บรรลุเป้าหมาย จึงหวังเป็นอย่างยิ่งว่าจะได้รับความร่วมมือจากท่านเป็นอย่างดี และผู้ศึกษาขอ การประเมินผลวิเคราะห์และสรุปในการศึกษาครังนีเท่านัน

คำชี้แจง **1)** แบบสอบถามนี้สำหรับ Quality Management Representative ในการทำงานเป็นผู้กรอกแบบสอบถาม

2) แบบสอบถามชุดนี้แบ่งออกเป็น 3 ส่วน คือ

ส่วนที่ 1 ข้อมูลทั่วไปของสถานประกอบการ

ส่วนที่ 2 ปัจจัยที่มีผลต่อความพึงพอใจของลูกค้าในการนำ Software มาช่วยจัดระบบคุณภาพ (ISO 9000)

ส่วนที่ 3 ทัศนคติและความคิดเห็นต่างๆที่มีต่อความพึงพอใจของลูกค้าในการนำ Software มาช่วยจัดระบบคุณภาพ **(ISO 9000)**

3) โปรดตอบคำถามตามความเป็นจริง และตอบทุกข้อคำถาม และกรุณาส่งแบบสอบถามกลับมาที่โทรสารหมายเลข **02-621-0373** , vutitom@yahoo.com

ดังนั้นข้าพเจ้าจึงใคร่ขอความกรุณาจากท่านในการให้ความมือตอบแบบสอบถามและขอขอบพระคุณล่วงหน้ามา **w** โอกาสนี้

_____

(นางสาววุฒิธร มหัทธนวงศ์วาน)

ผู้วิจัย

แบบสอบถาม

การสำรวจความพึงพอใจของลูกค้าในการนำ Software มาช่วยการจัดระบบคุณภาพ (ISO)

ส่วนที่ 1

1. ตำแหน่งหน้าที่ปัจจุบัน _____
2. ตำแหน่งหน้าที่รับผิดชอบปัจจุบัน (โปรดระบุ) _____
3. บริษัทท่านประกอบกิจการมาเป็นเวลา_____
4. จำนวนพนักงานในบริษัททั้งหมด _____ คน
5. บริษัทท่านนำ Software : ISO Master มาใช้เป็นเวลา _____
6. บริษัทท่านจัดอยู่ในประเภทอุตสาหกรรมประเภทใด (โปรดระบุ) _____

ส่วนที่ 2 ปัจจัยที่มีผลต่อความพึงพอใจของลูกค้าในการนำ Software มาช่วยการจัดระบบคุณภาพ (ISO)

โปรดทำเครื่องหมาย ลงในช่องที่ตรงกับระดับความพึงพอใจของท่าน

(5 111110V1 มีความพึงพอใจมากที่สุด 4 หมายถึง มีความพึงพอใจมาก

3 หมายถึง มีความพึงพอใจปากลาง 2 หมายถึง มีความพึงพอใจน้อย

1 หมายถึง มีความพึงพอใจน้อยมาก)

ลำดับ	ปัจจัยที่มีผลต่อความพึงพอใจของลูกค้าในการนำ Software มาช่วยการจัดระบบคุณภาพ (ISO)	5	4	3	2	1
1.	ความรวดเร็วในการอนุมัติเอกสาร โดยใช้ Electronic Signature					
2.	ลดปริมาณกระดาษในสำนักงาน					
3.	ระบบความปลอดภัยในการเก็บรักษาเอกสารสำคัญ					
4.	ค้นหาข้อมูลได้ถูกต้อง และรวดเร็ว					
5.	ข้อมูลมีความทันสมัยเพราะ Update ได้ง่าย					
6.	การติดต่อสื่อสารถูกต้อง ชัดเจน มีประสิทธิภาพ					
7.	ง่ายในการสรุปผล Internal Audit					
8.	การดึงข้อมูลกลับมาใช้ใหม่ของ Internal Audit มีความสะดวก รวดเร็ว					
9.	ประหยัดเวลาในการส่งผลการตรวจสอบ					
10.	ลดอัตรากำลังคนในการควบคุม IQA (Internal Quality Audit)					

ลำ	ปัจจัยที่มีผลต่อความพึงพอใจของลูกค้าในการนำ Software มาช่วยการจัดระบบคุณภาพ (ISO)	5	4	3	2	1
11.	ช่วยลดความผิดพลาดของระบบการปฏิบัติงานหลังจากที่พนักงานลาออกจากงาน					
12.	ตรวจสอบระบบความผิดพลาดได้อย่างถูกต้อง					
13.	ช่วยในการวิเคราะห์ข้อมูล และแก้ไขข้อมูลได้ถูกต้อง และรวดเร็ว					
14.	ลดขั้นตอนในการปฏิบัติงานเพราะมีการอนุมัติโดยใช้Electronic Signature					
15.	แจ้งวาระการประชุมไปยังหน่วยงานได้อย่างมีประสิทธิภาพ และครอบคลุมทุกเครือข่ายในองค์กร					
16.	ช่วยระบบการบันทึกรายงานการประชุม					
17.	แก้ไขบันทึกการประชุมได้รวดเร็ว สอดคล้องกับหัวข้อการประชุม					
18.	การทบทวนข้อมูลได้สะดวก รวดเร็ว ถูกต้อง					
19.	ช่วยในการกำหนดหัวข้อในการฝึกอบรม					
20.	ความรวดเร็วในการส่งตารางการฝึกอบรมไปยังหน่วยงานที่เกี่ยวข้อง					
21.	ความสะดวก และประหยัดพื้นที่ในการเก็บเอกสารการฝึกอบรม					
22.	ผู้ใช้โปรแกรมและผู้ที่พัฒนาโปรแกรมสามารถเรียนรู้ได้เร็ว					
23.	การจัดการด้านข้อมูลได้อย่างมีประสิทธิภาพ					
24.	ทบทวนนโยบายของฝ่ายจัดการได้ดีขึ้น					
25.	เชื่อมต่อระบบกับระบบการจัดการที่ดี					
26.	สรุปผลข้อมูล ประมวลผล นำเสนอ					
27.	ระบบมีความคล องตัว ปรับเปลี่ยนได้					
28.	**0014 It In 1S09000 ได้รวดเร็วขึ้น**					
29.	คุณภาพเอกสาร ดีขึ้น					
30.	คุณภาพการสื่อสาร ดีขึ้น					

ส่วนที่ 3 **ทัศนคติและความเห็นต่าง ที่มีต่อความพึงพอใจของลูกค้าในการนำ** Software **มาช่วยจัดระบบคุณภาพ (ISO)**

1. ท่านคิดว่าโปรแกรม ISO Master คุ้มค่าหรือไม่เมื่อเปรียบเทียบกับสิ่งที่ได้รับเมื่อนำมาใช้ โปรดระบุ

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2. ท่านคิดว่าโปรแกรมที่ใช้อยู่
   สอดคล้องกับการปฏิบัติงานในองค์กรของท่าน โปรดระบุ
   1. _____
   2. _____
   3. _____
   4. _____
   5. _____

ขอขอบพระคุณที่ท่านให้ความร่วมมือในการตอบแบบสอบถาม

การสำรวจความพึงพอใจของลูกค้าในการนำ Software มาช่วยการจัดระบบคุณภาพ (ISO)

ลำดับ	ปัจจัยที่มีผลต่อความพึงพอใจของลูกค้าในการนำ Software มาช่วยการจัดระบบคุณภาพ (ISO)	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Sample 7	Sample 8	Sample 9	Sample 10	Sample 11	Sample 12	Sample 13	Sample 14	Sample 15	Sample 16	Sample 17	Sample 18	[illegible]
1	ความรวดเร็วในการอนุมัติเอกสารอิเล็กทรอนิกส์ Electronic Signature	5	5	5		5	5	4	5	5	5	5	5	5	5	5	5	5	4	5
2		5	4	5		5	5	4	5	5	5	5	5	5	5	5	5	5	5	5
3	ระบบความปลอดภัยในการเก็บรักษาเอกสารสำคัญ	5	4	4		4	5	5	4	5	4	4	5	4	4	4	4	5	5	4
4	ค้นหาข้อมูลได้ถูกต้อง	4	4	5		4	4	4	4	4	4	4	4	4	4	4	4	5	5	4
5	ข้อมูลมีความทันสมัยเพราะ update ได้ง่าย	4	4	5		4	4	5	4	4	4	4	4	4	4	4	4	5	5	4
6	การติดต่อสื่อสารภายในองค์กรมีประสิทธิภาพ	4	5	4		4	4	4	4	4	4	4	4	4	4	4	4	5	5	4
7	ความถูกต้องในการสรุปผล Internal Audit	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	5	4	4
8	การดึงข้อมูลกลับมาใช้งานในส่วน Internal Audit มีความสะดวกรวดเร็ว	3	4	4		3	3	4	3	3	4	3	3	3	3	4	3	5	4	3
9	ระยะเวลาในการส่งผลการตรวจสอบ	4	5	5		3	4	4	3	4	4	3	4	3	3	3	3	5	5	4
10	ลดอัตรากำลังคนในการควบคุม IQA (Internal Quality Audit)	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	5	5	4
11	ช่วยลดความผิดพลาดของระบบการปฏิบัติงานหลังจากทีมงานลาออกจากงาน	4	4	4		4	4	5	4	4	4	4	4	4	4	4	4	5	4	4
12	ตรวจสอบระบบความผิดพลาดได้อย่างถูกต้อง	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	5	5	4
13	ช่วยในการวิเคราะห์ข้อมูลและแก้ไขข้อมูลได้ถูกต้องรวดเร็ว	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
14	ลดขั้นตอนในการปฏิบัติงานเพราะมีการอนุมัติอิเล็กทรอนิกส์ Electronic Signature	5	4	5		5	5	4	5	5	5	5	5	5	5	5	5	5	5	5
15	จัดวาระการประชุมปรับปรุงการทำงานมีประสิทธิภาพและครอบคลุมครบถ้วน	4	5	4		4	4	5	4	4	4	4	4	4	4	4	4	5	5	4
16	ระบบการบันทึกรายงานการประชุม	5	4	4		4	5	4	4	5	4	4	5	4	4	4	4	5	5	4
17	ก่อให้เกิดการประชุมเร็วรวดเร็วสอดคล้องกับข้อกำหนดประชุม	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	5	5	4
18	การทบทวนข้อมูลได้สะดวกรวดเร็วถูกต้อง	5	4	4		4	5	4	4	5	4	4	5	4	4	4	4	5	4	4
19	ช่วยในการกำหนดหัวข้อการฝึกอบรม	4	4	5		4	4	4	4	4	4	4	4	4	4	5	4	4	4	4
20	ความถูกต้องในการส่งตารางการฝึกอบรมตามที่กำหนด	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	5	5	4
21	ความสะดวกและปลอดภัยในพื้นที่การจัดการเอกสารการฝึกอบรม	5	4	5		5	5	4	5	5	5	5	5	5	5	5	5	5	5	5
22	ผู้ใช้โปรแกรมและผู้ที่พอจะแนะนำโปรแกรมให้เรียนรู้ได้ง่าย	3	4	3		3	3	4	3	3	3	3	3	3	3	3	3	4	3	3
23	การจัดการข้อมูลต่อย่างมีประสิทธิภาพ	5	4	4		4	5	4	4	5	4	4	5	4	4	4	4	5	4	4
24	ทบทวนบทบาทของผู้จัดการได้ดีขึ้น	5	4	4		4	5	5	4	5	4	4	5	4	4	4	4	5	4	4
25	ชี้แนะระบบการจัดการที่ดี	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	5	4	4
26	สรุปผลข้อมูลได้สะดวกนำเสนอ	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
27	ระบบมีความยืดหยุ่นปรับเปลี่ยนได้	4	4	4		4	4	5	4	4	4	4	4	4	4	4	4	5	4	4
28	ผู้เรียนรู้การใช้ IS รวดเร็วขึ้น	4	3	3		3	4	3	3	4	3	3	4	3	3	3	4	5	4	3
	คุณภาพเอกสารดีขึ้น	4	4	4		4	5	5	4	5	4	4	5	4	4	4	4	5	3	4
	คุณภาพการสอบ [illegible]	4	4	5		5	4	4	5	4	5	5	4	5	5	5	5	5	5	5
		4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	5	4	4

ลำดับ	ปัจจัยที่มีผลต่อความพึงพอใจของลูกค้าในการนำ Software มาช่วยการจัดระบบคุณภาพ (ISO)	ค่าเฉลี่ย
1	ความรวดเร็วในการอนุมัติเอกสาร โดยใช้ Electronic Signature	4.88
2	ลดปริมาณกระดาษในสำนักงาน	4.82
3	ระบบความปลอดภัยในการเก็บรักษาเอกสารสำคัญ	4.41
4	ค้นหาข้อมูลได้ถูกต้อง และรวดเร็ว	4.18
5	ข้อมูลมีความทันสมัยเพราะ Update ได้ง่าย	4.24
6	การติดต่อสื่อสารถูกต้อง ชัดเจน มีประสิทธิภาพ	4.18
7	ง่ายในการสรุปผล Internal Audit	4.06
8	การดึงข้อมูลกลับมาใช้ใหม่ของ Internal Audit มีความสะดวก รวดเร็ว	3.35
9	ประหยัดเวลาในการส่งผลการตรวจสอบ	3.76
10	ลดอัตรากำลังคนในการควบคุม IQA (Internal Quality Audit)	4.12
11	ช่วยลดความผิดพลาดของระบบการปฏิบัติงานหลังจากที่พนักงานลาออกจากงาน	4.12
12	ตรวจสอบระบบความผิดพลาดได้อย่างถูกต้อง	4.14
13	ช่วยในการวิเคราะห์ข้อมูล และแก้ไขข้อมูลได้ถูกต้อง และรวดเร็ว	4.06
14	ลดขั้นตอนในการปฏิบัติงานเพราะมีการอนุมัติโดยใช้ Electronic Signature	4.88
15	แจ้งวาระการประชุมไปยังหน่วยงานได้อย่างมีประสิทธิภาพ และครอบคลุมทุกเครือข่ายในองค์กร	4.24
16	ช่วยระบบการบันทึกรายงานการประชุม	4.35
17	แก้ไขบันทึกการประชุมได้รวดเร็ว สอดคล้องกับหัวข้อการประชุม	4.06
18	การทบทวนข้อมูลได้สะดวก 119141 ถูกต้อง	4.29
19	ช่วยในการกำหนดหัวข้อในการฝึกอบรLi	4.00
20	ความรวดเร็วในการส่งตารางการฝึกอบรมไปยังหน่วยงานที่เกี่ยวข้อง	4.12
21	ความสะดวก และประหยัดพื้นที่ในการเก็บเอกสารการฝึกอบรม	4.88
22	ผู้ใช้โปรแกรมและผู้ที่พัฒนาโปรแกรมสามารถเรียนรู้ได้เร็ว	3.18
23	การจัดการค้นข้อมูลได้อย่างมีประสิทธิภาพ	4.29
24	ทบทวนนโยบายของฝ่ายจัดการได้ดีขึ้น	435
25	เชื่อมต่อระบบกับระบบการจัดการที่ดี	4.06
26	สรุปผลข้อมูล ประมวลผล นำเสนอ	4.24
27	ระบบมีความค องตัว ปรับเปลี่ยนได้	4.12
28	ผู้เรียนรู้ ระบบ ISO9000 ได้รวดเร็วขึ้น	333
29	คุณภาพเอกสาร ดีขึ้น	4.29
30	คุณภาพการสื่อสาร ดีขึ้น	4.59
	ค่าเฉลี่ยโดยรวม	4.26

จำนวนทั้งหมดที่ส่งแบบสอบถาม	20	110
จำนวนผู้ตอบกลับมา	17	
คิดเป็นเปอร์เซนต์ (%)	85 %	

ลำดับ	ปัจจัยที่มีผลต่อความพึงพอใจของลูกค้าในการนำ software มาช่วยการจัดระบบคุณภาพ (ISO)	5	4	3	2	1	ค่าเฉลี่ย
	ความรวดเร็วในการอนุมัติเอกสาร โดยใช้ Electronic Signature	15	2	0	0	0	4.88
2	ลดปริมาณกระดาษในสำนักงาน	14	3	0	0	0	4.82
3	ระบบความปลอดภัยในการเก็บรักษาเอกสารสำคัญ	7	10	0	0	0	4.41
4	ค้นหาข้อมูลได้ถูกต้อง และรวดเร็ว	3	14	0	0	0	4.18
5	ข้อมูลมีความทันสมัยเพราะ Update ได้ง่าย	4	13	0	0	0	4.24
6	การติดต่อสื่อสารถูกต้อง ชัด mu มีประสิทธิภาพ	3	14	0	0	0	4.18
7	ง่ายในการสรุปผล Internal Audit	1	16	0	0	0	4.06
8	การดึงข้อมูลกลับมาใช้ใหม่ของ Internal Audit มีความสะดวก รวดเร็ว		4	12	0	0	3.35
9	ประหยัดเวลาในการส่งผลการตรวจสอบ	4	5	8	0	0	3.76
10	ลดอัตรากำลังคนในการควบคุม IQA (Internal Quality Audit)	2	15	0	0	0	4.12
11	ช่วยลดความผิดพลาดของระบบการปฏิบัติงานเนหลังจากทีพนักงานลาออกจากงาน	2	15	0	0	0	4.12
12	ตรวจสอบระบบความผิดพลาดได้อย่างถูกต้อง	?	12	0	0	0	4.14
13	ช่วยในการวิเคราะห์ข้อมูล และแก้ไขข้อมูลได้ถูกต้อง และรวดเร็ว	1	16		0	0	4.06
14	ลดขั้นตอนในการปฏิบัติงานเพราะมีการอนุมัติโดยใช้ Electronic Signature	15	2	0	0	0	4.88
15	แจ้งวาระการประชุมไปยังหน่วยงานได้อย่างมีประสิทธิภาพ และครอบคลุมทุกเครือข่ายในองค์กร	4	13	0	0	0	4.24
16	ช่วยระบบการบันทึกรายงานการประชุม	6	11	0	0	0	4.35
17	แก้ไขบันทึกการประชุมได้รวดเร็ว สอดคล้องกับหัวข้อการประชุม	1	16	0	0	0	4.06
18	การทบทวนข้อมูลได้สะดวก รวดเร็ว ถูกต้อง	5	12	0	0	0	4.29
19	itยในการกำหนดหัวข้อในการฝึกอบรม	0	17	0	0	0	4.00
20	ความรวดเร็วในการส่งตารางการฝึกอบรมไปยังหน่วยงานที่เกียวข้อง	2	15	0	0	0	4.12
21	ความสะดวก และประหยัดพื้นที่ในการเก็บเอกสารการฝึกอบรม	15	2	0	0	0	4.88
22	ผู้ใช้โปรแกรมและผู้ที่พัฒนาโปรแกรมสามารถเรียนรู้ได้เร็ว	0	3	14	0	0	3.18
23	การจัดการค้นข้อมูลได้อย่างมีประสิทธิภาพ	5	12	0	0	0	4.29
24	ทบทวนนโยบายของฝ่ายจัดการได้ดีขึ้น	6	11	0	0	0	4.35
25	เชื่อมต่อระบบกับระบบการจัดการทีดี	1	16	0	0	0	4.06
26	สรุปผลข้อมูล ประมวลผล นำเสนอ	4	13	0	0	0	4.24
27	ระบบมีความคล่องตัว ปรับเปลี่ยนได้	2	15	0	0	0	4.12
28	ผู้เรียนรู้ ระบบ 1509000 ได้รวดเร็วขึ้น	1	4	13	0	0	3.33
29	คุณภาพเอกสาร mitt	6	10	1	0	0	4.29
30	คุณภาพการสื่อสาร ดีขึ้น	10	7	0	0	0	459
	ค่าเฉลี่ยโดยรวม						4.26

จำนวนทั้งหมดที่ส่งแบบสอบถาม : **20**

จำนวนผู้ตอบกลับมา : **17**

คิดเป็นเปอร์เซนต์ (%) **85 %**

APPENDIX B

BSP DO
Business Solutions Provider Co.,Ltd.

BUSINESS SOLUTIONS PROVIDER **CO.,LTD.**
7/129 7th Floor., Baromrajchonnee Rd., Arunammarin,
Bangkok-Noi, Bangkok. 10700 THAILAND
Tel. (0)2884-9185/6, (0)2884-9183, (0)2884-9175 Fax: (0)2884-9145
http://www.bspc.co.th

ISOMaster Site Refference

COMPANY NAME	ADDRESS	TYPE OF BUSINESS
Sony Semiconductor (Thailand) Co., Ltd	140 Moo 5 Bangkadi Industrial Park, Tiwanon Rd., Tambol Bangkadi, Amphur Muang, Pathumthani 12000	Manufacture of circuits
Sony Magnetic Products (Thailand) Co., Ltd.	102/1 Moo 4 Lat Krabang Industrial Estate , Chalongkrung Rd., Lamplatiew, Lat Krabang, Bkk. 10520	Manufacture and assembly of cassette tape
Rayong Olefins Co., Ltd	271 Sukhumvit Rd., Maptaphut Muang District, Rayong 21150	Petrochemical
Dole (Thailand) Ltd	180 Moo.4 Hua-Hin Nongplub Rd, T.Nongplub, A.Hua-Hin, Prachuabkirikhan	Canned-Fruit Products
Unilever Thai Holding Co., Ltd..	411 Srinakarin Road, Suanloung, Bangkok 10250	Consumer Products
Rayong Electric Generating Company Limited.	35 Highway No.3191, Huay Pong, Amphur Muang, Rayong 21150	Electricity
Siam Wooden Products Co., Ltd.	140 Moo 7 Soi Watsriwareenoi, Km.18 Bangna-Trad Rd., Bang-Chalhong, Amphur Bangplee, Samuthprakarn 10540	Furniture Products
Thai Airways International PLC.	89 Vibhavadi Rangsit Rd., P.O.BOX 1075 Bangkok	Service
SSL Manufacturing (Thailand) Co., Ltd. The former of London Royal Consumer Products (Thailand) Ltd.; A member of London International Group	Wellgrow Industrial Estate Phase2, 100 Moo 5 Km.36 Bangna-Trad Rd., Bangsamak, Bangphakong, Chachoengsao 24130	Manufacturing
Mektec Manufacturing Corporation (Thailand) Ltd.	560 Moo 2, Bangpa-in Industrial Estate, Udomsorayuth Rd., Tambol Klong-Jik, Amphur Bangpa-in, Ayutthaya	Manufacturing
HANA Microelectronics PCL. (Lamphun)	EPZ, Northern Region Industrial Estate, 10112 Moo 4 Lamphun 51000 Thailand	Manufacture of circuits
Thai Foods International Co., Ltd.	18 Moo 5 Suchart Pattana Rd., Bangsaipa, Banglen, Nakornpathorm	Manufacturing
ABB Limited.	297 Moo 4, Bangpoo Industrial Estate Pracksa District, A.Muang, Samutprakarn	Manufacture of circuits

BSP
Business Solutions Provider Co .,Ltd.

BUSINESS SOLUTIONS PROVIDER **CO.,LTD.**
7/129 7th Floor., Baromrajchonnee Rd., Arunammarin,
Bangkok-Noi, Bangkok. 10700 THAILAND
Tel. (0)2884-9185/6, (0)2884-9183, (0)2884-9175 Fax: (0)2884-9145
http://www.bspc.co.th

ISOMaster Site Refference

COMPANY NAME	ADDRESS	TYPE OF BUSINESS
LFD Manufacturing Limited	21/7 Moo 6, Kookot, Lamlukka Pathumthani 12130	Manufacture of circuits
Khanom Electricity Generating Company Limited. (KEGCO)	112 Moo 1 T.Tongnean, A.Khanom, Nakornsrithammarat 80210	Electricity
Muang Thai Life Assurance Co., Ltd.	250 Ratchadapisek Rd., Samsen-Nok, Huaykwang Bangkok 10320	Assurance
Petroleum of Authority of Thailand (Oil)	2 Adnarong Rd., Klongtoey, Phakanong, Bangkok 10250	OIL
EGCO Engineering & Service Co., Ltd.	35 Highway No.3191, Huay Peng, Amphur Muang, Rayong 21150	Services

APPENDIX C

"Master" Quality Product

No Matter What Your Business is,
We Always Support You.

The intelligent Electronic Documentation & Workflow Management

to help you achieve ISO 9001:2000, ISO. 14000, QS 900.0, มอก. 1800.0

Document & Data Control Feature

* Cover all document types required by ISO 9001: 2000
* Pre-Define Document Format
• Electronic Workflow capability with Electronic Signature
• Programmable workflow of document type and area
• Security control down to document level
• Document Status Tracking
* Automatic Notification to Document Readers
* Automatic remove obsolete document after new document is announced
• Change request record tracing from the current document
* Real Time Master List for easy viewing of Controlled Document.
* A powerful Full Text Search (can search every text in a database include file attachment)
* Distribution Control via Local Area Network or Intranet or Internet
* Storage, size is very compact
* Support Multiple user
* Other Windows application can be integrated, such as Visio, Microsoft Excel, MS Word, ...etc.
* Multimedia information can be integrated

IQA VC/1i

• General IQA Checklist format (can he pre-written to suite the need of an organization)
• On-line IQA Plan
• Automatic Notification to all involved personnel
• On-line Posting Audit Report
• Link to Open CAR by clicking a button
• On-line link to Management Review Agenda
• Multiple viewing with easy record retrievable for Audit Checklist, Audit Master Plan, Audit Sub-plan, Audit Report, Auditor Profile

Corrective Action Request Feature

• Open CAR On-line
* Send to responsible personnel for investigating the root cause via network on-line.
• Record all investigation, root cause analysis, corrective action in single CAR form format.
* CAR record can link to Management Review and/or can be on-line reviewed by the Management.
* Electronic sign the CAR.
* CAR record retention in software
* Easy retrievable via navigator view
• CAR Log Record

Review Feature

• On-line Management Review agenda issued to all personnel via network.
• On-line notify and confirm of Management Review schedule date.
* On-line record the meeting minutes in Management Review form.
* On-line issue the meeting minutes and assign actions to all concerns via network.
* Electronic sign to close out the corrective action items.
* Any meeting material such as charts, statistics, tables, be integrated or link to be reviewed.
* Management Review record can viewed at all status during process workflow.
  - *AIR Agenda*
  - *AIR Minutes*
  - *MR Action items*

Training Feature

• On-line Training Plan
• Providing List of Qualified Instructor
• On-line notification, confirmed, conduct training, evaluation, completed status
* Keep evaluation record in software file
* Training Needs
* Course List
* All Training records are seen and easy retrieving via navigator view

BUSINESS SOLUTIONS PROVIDER CO., LTD.
7th Floor Central Pinklao Office Tower, 7/129 Baromrajchonnee Rd., Arunamarin, Bangkok-Noi, BKK IC.
Tel. (0)2884-9183, (0)2884-9175, (0)288491-85/86 Fax : (0)2884-9145
email : sales@bspc.co.th http://www.bspc.co.th

ISO Master™
Quality Product

No Matter What Your Business *is,*
We *Always* Support You

The intelligent Electronic Documentation & Workflow Management to help you achieve ISO 9000 Quality System

Document & Data Control Feature and Benefit

Features

- **Cover all document types required by ISO 9000.**
- **Pre-Define Document Format for ISO 9000 requirement.**
- **Electronic Workflow capability with Electronic Signature.**
- **Programmable workflow down to document type and area.**
- **Security control down to document level.**
- **Document Status Tracking**
- **Automatic Notification to Document Readers.**
- **Automatic remove obsolete document after new document is announced.**
- **Change request record tracing from the current document.**
- **Document Master List for easy viewing of sorted Document;**
- **A powerful Full Text Search (can search every text in any field in a database include file attachment)**
- **Distribution Control via Local Area Network or Intranet or Internet.**
- **Storage size is very compact.**
- **Support Multiple user**
- **Other Windows application can be integrated, such as Visio, Microsoft Excel, MS Word, ... etc.**
- **Multimedia information can be integrated.**

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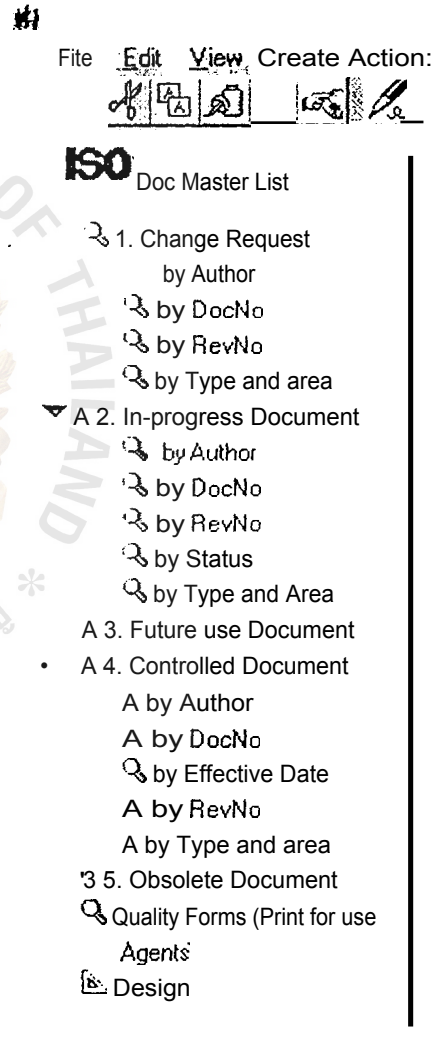
Document & Data Control Feature and Benefit

Benefit

'Speed up the document approval process (using Electronic Signature, accepted by Certified Body around the world)
•Easy Document Management and Maintenance
•Low cost of Document Distribution via Workstation, Replication, Intranet, Internet
•Save printing cost
•Compact Storage size (because electronic document can be archived in CDs, Tape or Hard-Disk)
•Fast document retrieve
- *•Via View index for example, Index by .... etc.*
- *•Via Full Text Search (search for any word, combination in any of the document field in Database)*
- *•Referring between Documents can be done easily via Document Link (for example, Current Document link to Revision History Record and further to Change Request)*

•Alert and Notify can be done automatically via a use of automatic Agent
•Better Security
- *•Authentication*
- *'Database Access Control Levels*
- *•View Access Control*
- *•Document Access Control (Document Read access)*
- *•Document Section Access Control*
- *•Field Encryption for a very secure document*



TM

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Internal Quality Audit Feature and Benefit

Features

•General IQA Checklist format (can be pre-written to suite the need of an organization).
•On-line IQA Plan
•Automatic Notification to all involved personnel.
•On-line Posting Discrepancy Record
•Link to Open CAR by clicking a button.
•On-line link to Management Review Agenda.
•Multiple viewing with easy record retrievable for Audit Checklist, IQA Plan, and Discrepancy Record view.
•Documents can be sorted by;

Benefit

•All areas can read the **IQA Plan** via network on-line, make communication more effective
•All areas concerns be **notified of audit schedules** and can confirm back to Auditor via network on-line.
•**Save manpower** of conducting the Internal Quality Audit
•**No hard-copied records** required

Effective record retention and easy retrievable records will satisfy the third party auditor.

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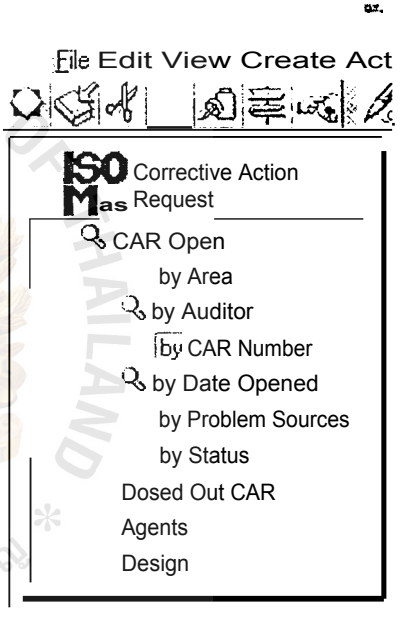
Corrective Action Request Feature and Benefit

Features

- **Open CAR** On-line
- Send to 'responsible personnel for **investigating the root cause via network** on-line.
- Record all investigation, root cause analysis, corrective action in **single CAR form format.**
- **CAR record can link to Management Review** and/or can be on-line reviewed by the Management.
- **Electronic sign** the CAR record.
- CAR **record retention** in software.
- Easy **retrievable** via navigator view;



Benefit

- **CAR process is done on network, make** it more effective and low operating cost.
- Responsible area/personnel can easily record any investigation, root cause analysis, and corrective action on-line **without issuing any hard-copied paper.**
- Clarified and effective communication among the area concerns.
- Management Review can be conducted on-line by **reviewing CAR records.**
- The management can easily **electronic sign closing out the CAR.**
- **Low cost CAR** record retention, **no hard-copies required.**

Effective record retention and easy retrievable records will satisfy the third party auditor.

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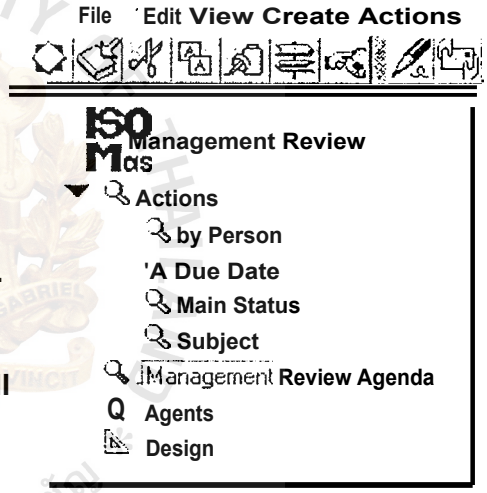
Management Review Feature and Benefit

Features

•On-line **Management Review agenda issued to all personnel via network.**
•On-line notify and confirm of Management Review schedule date.
•On-line record the meeting minutes in Management Review form.
•On-line issue the meeting minutes and assign actions to all concerns via network.
•Electronic sign to close out the corrective action.
•Any **meeting material such as charts, statistics, tables, be integrated or link to be reviewed.**
•Management **Review record can be viewed at all status during process workflow;**



Benefit

•Management Review Meeting agenda can be effectively communicated to all areas via network.
•Meeting minutes can be recorded on-line during the meeting.
'Easy to follow-up and track the corrective action in accordance with the meeting minutes.
•The management can review any statistics, measurements, proposal, and information on-line.
•Low operating cost, because no hard-copy and transparent presentation required.

Effective record retention and easy retrievable records will satisfy the third party auditor.

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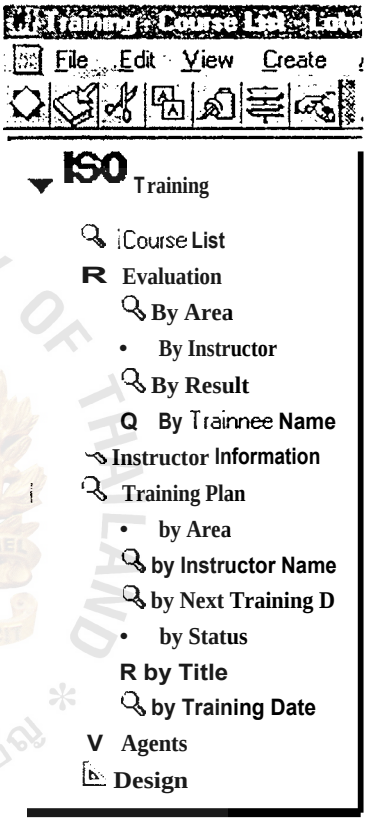
Training Feature and Benefit



Features

- **On-line Training Plan**
  -Providing List of Qualified Instructor
- **On-line notification, confirmed, conduct training, evaluation, completed status**
- Keep **evaluation record in software file**
- All **Training records are seen and easy retrieving via navigator view;**

All documents/records can be electronic signed

Benefit

- **Training Course can be easily pre-defined, make it more easier to conduct the training.**
- **Training Plan is Pre-defined make it the effective communication to all area concerns.**
- Pre-defined **of qualified instructor to each course/job title.**
- Pre-defined **of Evaluation Criteria to run the individual test/training result.**
- **Low cost to keep all Training records in software media instead of hard-copied records.**
- **Training Record retention and retrieving made easy in a large organization.**
- **Easy retrieving of all training records for auditor to review.**

APPENDIX D

SINGAPORE STANDARD

SS ISO 9001 : 2000

(ICS 03.120.10)

Quality management systems – Requirements

Published by
Singapore Productivity and Standards Board
1 Science Park Drive
Singapore 118221

PSB
SINGAPORE

SINGAPORE STANDARD

SS ISO 9001 : 2000

(ICS 03.120.10)

Quality management systems Requirements

Director
Centre for Standardisation
Singapore Productivity and Standards Board
1 Science Park Drive
Singapore 118221
Telephone: 2786666 Telefax: 2786665
Email: cfs@psb.gov.sg

ISBN 9971-67-822-5

This Singapore Standard was approved by the Standards Council of Singapore on 16 December 2000.

First published, 1988
First revision, 1994
Second revision, 2000

The Special Technical Committee on Quality Management and Quality Assurance appointed by the Standards Council and responsible for the preparation of this standard consists of the representatives from the following organisations:

	Name	Organisation
Chairman	: Mr Lau Joo Ming	*Housing & Development Board*
Secretary	Miss Chua Mui Kiau	*Singapore Productivity and Standards Board*
Members	Mr Chia Yong Kwang	*Singapore Institute of Architects*
	Mr Chuah Choo Huat	*Singapore Productivity and Standards Board*
	Mr Ho Juan Yang	*Singapore Quality Institute*
	Assoc Prof Lim Choon Seng	*Nanyang Technological University*
	Prof Lennie Lim Enk Ng	*Institution of Engineers Singapore*
	Mr Phua Kim Chua	*Singapore Accreditation Council*
	Mr Png Choo Ling	*Singapore Confederation of Industries*
	Mr Tan Boon Kee	*Building and Construction Authority*
	Ms Teo Siew Hong	*Infocomm Development Authority of Singapore*
Co-opted Member	Mr Tan Tiong Keat	*Individual Capacity*

The Working Group appointed by the Special Technical Committee on Quality Management and Quality Assurance to assist in the preparation of this standard comprises the following members:

	Name	Organisation
Convenor	: Mr Phua Kim Chua	*Singapore Accreditation Council*
Members	: Mr Cheong Mun Sang	*Ngee Ann Polytechnic*
	Mr Tan King Bing	*Housing & Development Board*

Contents

National Foreword

This Singapore Standard was prepared by the Special Technical Committee on Quality Management and Quality Assurance under the direction of the Standards Council of Singapore. This standard is a revision of SS ISO 9001:1994 and is identical with ISO 9001:2000. SS ISO 9001:2000 cancels and replaces SS ISO 9001:1994 together with SS ISO 9002:1994 and SS ISO 9003:1994.

Organisations which have used SS ISO 9002:1994 and SS ISO 9003:1994 in the past may use this standard by excluding certain requirements in accordance with clause 1.2.

Where the words 'International Standard' appear, they should be interpreted as 'Singapore Standard'. The references to International Standards shall be replaced by the following Singapore Standards:

International Standard	Corresponding Singapore Standard
ISO 9000 : 2000	SS ISO 9000 : 2000 Quality management systems — Fundamentals and vocabulary
ISO 9004 : 2000	SS !SO 9004 : 2000 Quality management systems — Guidelines for performance improvements

Annexes A and B of this Singapore Standard are for information only.

NOTE

Singapore Standards are subject to periodic review to keep abreast of technological changes and new technical developments. The revisions of Singapore Standards are announced through the issue of either amendment slips or revised editions.

Compliance with a Singapore Standard does not exempt users from legal

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance,* Subcommittee SC 2, *Quality systems.*

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term "Quality assurance". This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows That customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies

Do: implement the processes.

Check: monitor and measure processes and against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

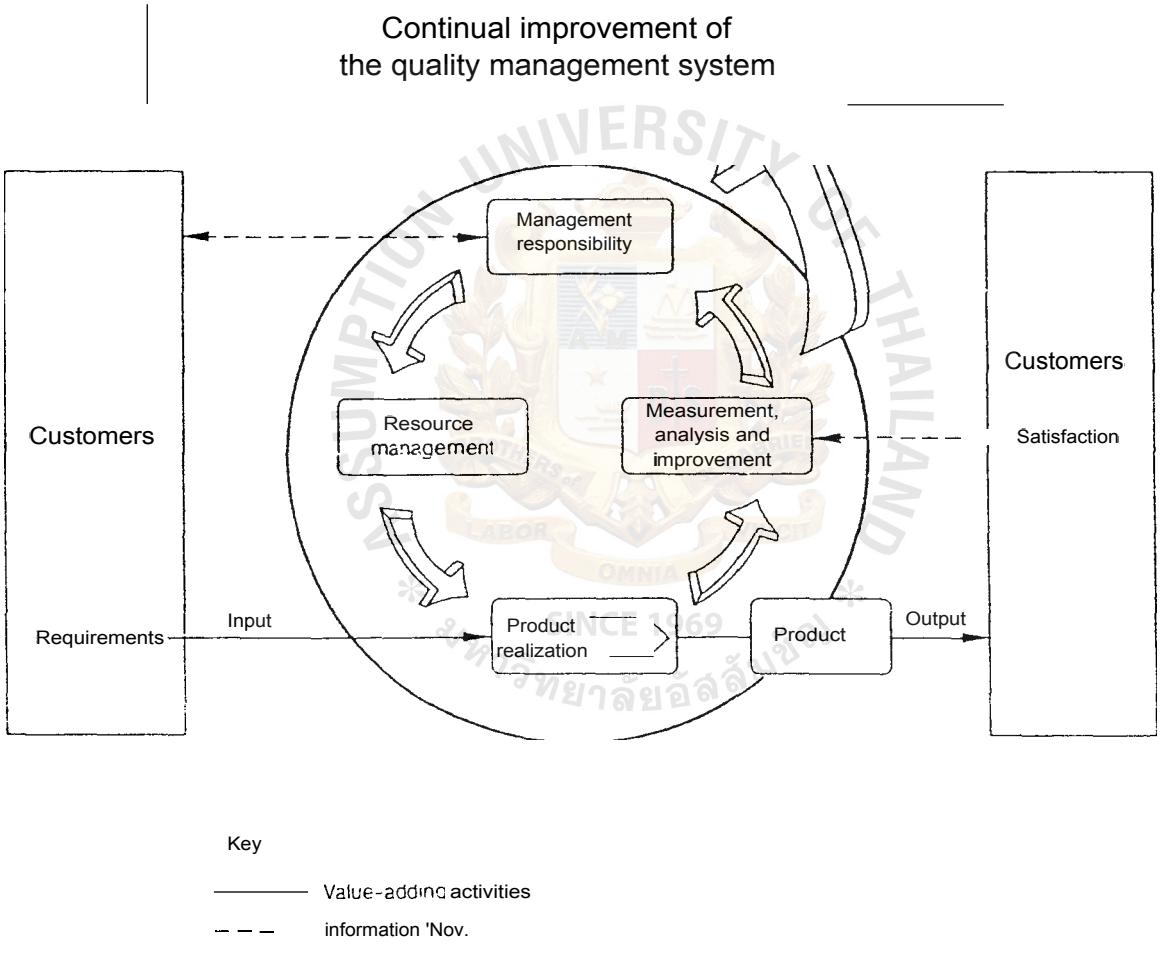


Figure 1—Model of a process-based quality management system

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

;SO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

OA_ Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Quality management systems — Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not 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.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier ——— organization ——— customer

The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

8) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

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 analyse these processes, and

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

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

) documented statements of a quality policy and quality objectives,

h) a 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, and

c) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term "documented procedure" appears within this International Standard, this 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 of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

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

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

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

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

4.2.3 Control of documents

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

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-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, and

g) to prevent the unintended use of obsolete documents. and to apply suitable identification, to them if thev 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 quality management 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.

5 Management responsibility

5.1 Management commitment

management shah provide evidence of its commitment to the development and implementation of the duality management system and continually improving its effectiveness by

communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.

quality bait%

ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction

5.3 Quality policy

Top management shall ensure that the 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, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

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

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

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

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 the quality management system are established, implemented and maintained,

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

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management 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 the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

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

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

7 Product realization

7.1 Planning of 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 the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product:

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization'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, and

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 (see 4.2.4).

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 internet 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 with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 Design and development planning

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 stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for ;:s safe and proper use.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records o the results of the reviews and any necessary actions shall be maintained (see

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, .as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and-product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

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

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

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) requirements for qualification of personnel, and

c) quality management system requirements.

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

7.4.3 Verification of purchased 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 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 conditions 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 monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

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

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes 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 is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4), and

e) revalidation.

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 the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

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 the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into 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 (see 4.2.4).

NOTE Customer property can include intellectual property.

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 shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

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 (see 7.2.1).

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 to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 arid ISO 10012-2 for guidance

8 Measurement, analysis and improvement

8.1 General

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

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

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

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

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.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the 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.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2 4).

Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform 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 defined in a documented procedure.

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

a) by taking action to eliminate the detected nonconformity;

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

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management 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 (see 8.2.1),

b) conformity to product requirements (see 7.2.1),

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

8.5 Improvement

8.5.1 Continual improvement

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

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (see 4.2.4), and

f) reviewing corrective action taken

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A 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 (see 41.4), and

e) reviewing preventive action taken.

Annex A
(informative)

Correspondence between ISO 9001:2000 and ISO 14001:1996

Table A.1 — Correspondence between ISO 9001:2000 and ISO 14001:1996

SO 9001:2000		1S0 14001:1996	
Introduction			Introduction
General	0.1		
Process approach	0.2		
Relationship with ISO 9004	0.3		
Compatibility with other management systems	0.4		
Scope	1	1	Scope
General	1.1		
Application	1.2		
Normative references	2	2	Normative references
Terms and definitions	3	3	Definitions
Quality management system	4	4	Environmental management system requirements
General requirements	4.1	4.1	General requirements
Documentation requirements	4.2		
General	4.2.1	4.4.4	Environmental management system documentation
Quality manual	4.2.2	4.4.4	Environmental management system documentation
Control of documents	4.2.3	4.4.5	Document control
Control of records	4.2.4	4.5.3	Records
Management responsibility	5	4.4.1	Structure and responsibility
Management commitment	5.1	4.2	Environmental policy
		4.4.1	Structure and responsibility
Customer focus	5.2	4.3.1	Environmental aspects
		4.3.2	Legal and other requirements
Quality policy	5.3	4.2	Environmental policy
Planning	5.4	4.3	Planning
Quality objectives	5.4.1	4.3.3	Objectives and targets
Quality management system planning	5.4.2	4.3.4	Environmental management programme(s)
Responsibility, authority and communication	5.5	4.1	General requirements
Responsibility and authority	5.5.1	4.4.1	Structure and responsibility
Management representative	5.5.2		
Internal communication	5.5.3	4.4.3	Communication
Management review	5.6	4.6	Management review
General	5.6.1		
Review input	5.6.2		
Review output	5.6.3		
Resource management	6	4.4.1	Structure and responsibility
Provision of resources	6.1		
Human resources	6.2		
General	6.2.1		
Competence, awareness and training	6.2.2	4.4.2	Training, awareness and competence
Infrastructure	6.3	4.4.1	Structure and responsibility
Work environment	6.4		

Table A.1 — Correspondence between ISO 9001:2000 and ISO 14001:1996 *(continued)*

ISO 9001:2000		ISO 14001:1996	
Product realization	7	4.4 4.4.6	Implementation and operation Operational control
Planning of product realization	7.1	4.4.6	Operational control
Customer-related processes	7.2		
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6	Environmental aspects Legal and other requirements Operational control
Review of requirements related to the product	7.2.2	4.4.6 4.3.1	Operational control Environmental aspects
Customer communication	7.2.3	4.4.3	Communications
Design and development	7.3		
Design and development planning	7.3.1	4.4.6	Operational control
Design and development inputs	7.3.2		
Design and development outputs	7.3.3		
Design and development review	7.3.4		
Design and development verification	7.3.5		
Design and development validation	7.3.6		
Control of design and development changes	7.3.7		
Purchasing	7.4	4.4.6	Operational control
Purchasing process	7.4.1		
Purchasing information	7.4.2		
Verification of purchased product	7.4.3		
Production and service provision	7.5	4.4.6	Operational control
Control of production and service provision	7.5.1		
Validation of processes for production and service provision	7.5.2		
Identification and traceability	7.5.3		
Preservation of product	7.5.5		
Control of monitoring and measuring devices	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement	8	4.5	Checking and corrective action
General	18.1	4.5.1	Monitoring and measurement
Monitoring and measurement	18.2		
Customer satisfaction	8 2 1		
Internal audit	8.2.2	4.5.4	Environmental management system audit
Monitoring and measurement of processes	8.2.3	4.5.1	Monitoring and measurement
Monitoring and measurement of product			
Control of nonconforming product	8.3	4.5.2 4.4.7	Nonconformance and corrective and preventive Emergency preparedness and response
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement	8.5	4.2	Environmental policy
Continual improvement	8.5.1	4.3.4	Environmental management programme(s)
Corrective action		4.5.2	Nonconformance and corrective and preventive action
Prevention action			

Table A2— Correspondence between ISO 14001:1996 and ISO 9001:2000

ISO 14001:1996		ISO 9001:2000	
Introduction	—	0	Introduction
		0.1	General
		0.2	Process appraoch
		0.3	Relationship with ISO 9004
		0.4	Compatibility with other management systems
Scope	1	1	Scope
		1.1	General
		1.2	Application
Normative references	2	2	Normative references
Definitions	3	3	Terms and definitions
Environmental management system requirements	4	4	Quality management system
General requirements	4.1	4.1	General requirements
		5.5	Responsibility, authority and communication
		5.5.1	Responsibility and authority
Environmental policy	4.2	5.1	Management commitment
		5.3	Quality policy
		8.5	Improvement
Planning	4.3	5.4	Planning
Environmental aspects	4.3.1	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
Legal and other requirements	4.3.2	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
Objectives and targets	4.3.3	5.4.1	Quality objectives
Environmental management programme(s)	4.3.4	5.4.2	Quality management system planning
		8.5.1	Continual impovement
Implementation and operation	4.4	7	Product realization
		7.1	Planning of product realization
Structure and responsibility	4.4.1	5	Management responsibility
		5.1	Management commitment
		5.5.1	Responsibility and authority
		5.5.2	Management representative
		6	Resource management
		6.1	Provision of resources
		6.2	Human resources
		6.2.1	General
		6.3	Infrastructure
		6.4	Work environment
Training, awareness and competence	4.4.2	6.2.2	Competence, awareness and training
Communication	4.4.3	5.5.3	Internal communication
		7.2.3	Customer communication
Environmental management system documentation	4.4.4	4.2	Documentation requirements
		42.1	General
		4.2.2	Quality manual

Table A.2 — Correspondence between ISO 14001:1996 and ISO 9001:2000 *(continued)*

ISO 14001:1996		ISO 9001:2000	
Document control	4.4.5	4.2.3	Control of documents
Operational control	4.4.6	**7**	**Product realizaton**
		7.1	Plannng of product realization
		7.2	Customer-related processes
		7.2.1	Determination of requirements related to the prou
		7.2.2	Review of requirements related to the product
		7.3	Design and development
		7.3.1	Design and development planning
		7.3.2	Design and development inputs
		7.3.3	Design and development outputs
		7.3.4	Design and development review
		7.3.5	Design and development verification
		7.3.6	Design and development validation
		7.3.7	Control of design and development changes
		7.4	Purchasing
		7.4.1	Purchasing process
		7.4.2	Purchasing information
		7.4.3	Verification of purchased product
		7.5	Production and service provision
		7.5.1	Control of production and service provision
		7.5.3	Identification and traceability
		7.5.4	Customer property
		7.5.5	Preservation of product
		7.5.2	Validation of processes for production and service provision
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking and corrective action	4.5	**8**	**Measurement, analysis and improvement**
Monitoring and measurement	4.5.1	7.6	Control of monitoring and measuring devices
		8.1	General
		8.2	Monitoring and measurement
		8.2.1	Customer satisfaction
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
		8.4	Analysis of data
Nonconformance and corrective and preventive action	4.5.2	8.3	Control of nonconforming product
		8.5.2	Corrective action
		8.5.3	Preventive action
Records	4.5.3	4.2.4	Control of records
Environmental management system audit	4.5.4	8.2.2	Internal audit
Management review	4.6	5.6	Management review
		5.6.1	General
		5.6.2	Review input
		5.6.3	Review output

Annex B
(informative)

Correspondence between ISO 9001:2000 and ISO 9001:1994

Table B.1 — Correspondence between ISO 9001:1994 and ISO 9001:2000

ISO 9001:1994	ISO 9001:2000
1 Scope	1
2 Normative reference	2
3 Definitions	3
4 Quality system requirements [title only]	
4.1 Management responsibility [title only]	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization [title only]	
4.1.2.1 Responsibility and authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management representative	5.5.2
4.1.3 Management review	5.6.1 + 8.5.1
4.2 Quality system [title only]	
4.2.1 General	4.1 + 4.2.2
4.2.2 Quality system procedures	4.2.1
4.2.3 Quality planning	5.4.2 + 7.1
4.3 Contract review [title only]	
4.3.1 General	
4.3.2 Review	5.2 + 7.2.1 + 7.2.2 + 7.2.3
4.3.3 Amendment to a contract	7.2.2
4.3.4 Records	7.2.2
4.4 Design control [title only]	
4.4.1 General	
4.4.2 Design and development planning	7.3.1
4.4.3 Organizational and technical interfaces	7.3.1
4.4.4 Design input	7.2.1 + 7.3.2
4.4.5 Design output	7.3.3
4.4.6 Design review	7.3.4
4.4.7 Design verification	7.3.5
4.4.8 Design validation	7.3.6
4.4.9 Design changes	7.3.7
4.5 Document and data control [title only]	
4.5.1 General	4.2.3
4.5.2 Document and data approval and issue	4.2.3
4.5.3 Document and data changes	4.2.3
4.6 Purchasing [title only]	
4.6.1 General	
4.6.2 Evaluation of subcontractors	7.4.1
4.6.3 Purchasing data	7.4.2
4.6.4 Verification of purchased product	7.4.3

Table 6.1 — Correspondence between ISO 9001:1994 and ISO 9001:2000 *(continued)*

ISO 9001:1994	ISO 9001:2000
1.7 Control of customer-supplied product	7.5.4
1.8 Product identification and traceability	7.5.3
1.9 Process control	6.3 + 6.4 + 7.5.1 + 7.5.2
4.10 Inspection and testing [title only]	
4.10.1 General	7.1 + 8.1
1.10.2 Receiving inspection and testing	7.4.3 + 8.2.4
1.10.3 In-process inspection and testing	8.2.4
1.10.4 Final inspection and testing	8.2.4
1.10.5 Inspection and test records	7.5.3 + 8.2.4
4.11 Control of inspection, measuring and test equipment [title only]	
4.11.1 General	7.6
4.11.2 Control procedure ,	7.6
4.12 Inspection and test status	7.5.3
4.13 Control of nonconforming product [title only]	
4.13.1 General	8.3
4.13.2 Review and disposition of nonconforming product	8.3
4.14 Corrective and preventive action [title only]	
4.14.1 General	8.5.2 + 8.5.3
4.14.2 Corrective action	8.5.2
4.14.3 Preventive action	8.5.3
4.15 Handling, storage, packaging, preservation & delivery [title only.	
4.15.1 General	
4.15.2 Handling	7.5.5
4.15.3 Storage	7.5.5
4.15.4 Packaging	7.5.5
4.15.5 Preservation	7.5.5
4.15.6 Delivery	7.5.1
4.16 Control of quality records	4.2.4
4.17 Internal quality audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
4.19 Servicing	7.5.1
4.20 Statistical techniques [title only]	
4.20.1 Identification of need	8.1 + 8
4.20.2 Procedures	8.1 + 8.2 8.4

Table B.2 — Correspondence between ISO 9001:2000 and ISO 9001:1994

ISO 9001:2000	ISO 9001:1994
1 Scope	**1**
1.1 General	
1.2 Application	
2 Normative reference	**2**
3 Terms and definitions	**3**
4 Quality management system [title only]	
4.1 General requirements	4.2.1
4.2 Documentation requirements [title only]	
4.2.1 General	4.2.2
4.2.2 Quality manual	4.2.1
4.2.3 Control of documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of records	4.16
5 Management responsibility [title only]	
5.1 Management commitment	4_1.1
5.2 Customer focus	4.3.2
5.3 Quality policy	4.1.1
5.4 Planning [title only]	
5.4.1 Quality objectives	4.1.1
5.4.2 Quality management system planning	4.2.3
5.5 Responsibility, authority and communication [title only]	
5.5.1 Responsibility and authority	4.1.2.1
5.5.2 Management representative	4.1.2.3
5.5.3 Internal communication	
5.6 Management review [title only]	
5.6.1 General	4.1.3
5.6.2 Review input	
5.6.3 Review output	
6 Resource management [title only]	
6.1 Provision of resources	4.1.2.2
6.2 Human resources [title only]	
6.2.1 General	4.1.2.2
6.2.2 Competence, awareness and training	4.18
6.3 Infrastructure	4.9
6.4 Work environment	4.9
7 Product realization [title only]	
7.1 Planning of product realization	4 + 4.10.1
7.2 Customer-related processes [title only]	
7.2.1 Determination of requirements related to the product	4.3.2 4.4.4
7.2.2 Review of requirements related to the product	4.3.2 + 4.3.3 + 43.4
7.2.3 Customer communication	4.3.2
7.3 Design and development [title only]	
7.3.1 Design and development planning	
7.3.2 Design and development inputs	

Table B.2 — Correspondence between ISO 9001:2000 and ISO 9001:1994 *(continued)*

ISO 9001:2000	ISO 9001:1994
7.3.3 Design and development outputs	4.4.5
7.3.4 Design and development review	4.4.6
7.3.5 Design and development verification	4.4.7
7.3.6 Design and development validation	4.4.8
7.3.7 Control of design and development changes	4.4.9
7.4 Purchasing [title only]	
7.4.1 Purchasing process	4.6.2
7.4.2 Purchasing information	4.6.3
7.4.3 Verification of purchased product	4.6.4 + 4.10.2
7.5 Production and service provision [title only]	
7.5.1 Control of production and service provision	4.9 + 4.15.6 + 4.19
7.5.2 Validation of processes for production and service provision	4.9
7.5.3 Identification and traceability	4.8 + 4.10.5 + 4.12
7.5.4 Customer property	4.7
7.5.5 Preservation of product	4.15.2 + 4.15.3 + 4.15.4 + 4.15.5
7.6 Control of monitoring and measuring devices	4.11.1 + 4.11.2
8 Measurement, analysis and improvement [title only]	
8.1 General	4.10.1 + 4.20.1 + 4.20.2
8.2 Monitoring and measurement [title only]	
8.2.1 Customer satisfaction	
8.2.2 Internal audit	4.17
8.2.3 Monitoring and measurement of processes	4.17 + 4.20.1 + 4.20.2
8.2.4 Monitoring and measurement of product	4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2
8.3 Control of nonconforming product	4.13.1 + 4.13.2
8.4 Analysis of data	4.20.1 + 4.20.2
8.5 Improvement [title only]	
8.5.1 Continual improvement	4.1.3
8.5.2 Corrective action	4.14.1 + 4.14.2
8.5.3 Preventive action	4.14.1 + 4.14.3

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3) Available from website: http://www.iso.ch
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THE SINGAPORE PRODUCTIVITY AND STANDARDS BOARD

The Singapore Productivity and Standards Board (PSB) is a statutory board established in April 1996, with the integration of the functions of the National Productivity Board (NPB) and the Singapore Institute of Standards and Industrial Research (SISIR) and the takeover of the small and medium-sized enterprise (SME) development function from the Economic Development Board (EDB). It is governed by a board of directors comprising representatives from government, employers, trade unions and academia.

While NPB's activities focused on training, productivity and promotion, SISIR's work centered on technology, quality, standards and industrial research. With the formation of PSB, synergy is derived by putting the "soft" and "hard" aspects of productivity with the same organisation so that PSB is greater than the sum of NPB and SISIR.

PSB's mission is to raise the productivity and enhance Singapore's competitiveness and economic growth. The Board's vision is to be a leading player with a global perspective in matters related to productivity and standards.

One of the functions of PSB is the establishment of a national standardisation programme to support industrialisation in Singapore. The Board is vested with the authority to appoint a Standards Council to advise on the preparation, publication and promulgation of Singapore Standards and Technical References and the promotion of their adoption.

Singapore Standards are in the form of specifications for materials and products, codes of practice, methods of test, nomenclature, etc. The standards are drawn up by various Technical Committees appointed by the Product Standards Committees (for product standards), the Practice Committees (for codes of practice) or the Standards Committees (for both product standards and codes of practice), the final approval body being the Standards Council. To ensure adequate representation of all viewpoints in the preparation of Singapore Standards, all Committees appointed consist of representatives from various interest groups which include government agencies, professional bodies, tertiary institutions and consumer, trade and manufacturing organisations.

Technical References are documents developed to help meet urgent industry demand for specifications or requirements on a particular product or process in an area where there is an absence of reference standards. Unlike Singapore Standards, they are issued without full consensus, as public comments are not sought. Technical References will be reviewed with a possibility of processing them to Singapore Standards.

PSB operates a number of national certification schemes.

The Board is the owner of the Certification Marks shown in Figures 1 and 2. These Marks can be used only by companies certified under the Singapore Quality Mark Certification Scheme and Product Listing Scheme operated by PSB. The presence of these Marks on a product with the inscription "Certified/Listed to Singapore Standard" is an assurance that either the product has been produced to comply with requirements of the relevant Singapore Standard under a system of supervision, control and testing operated during manufacture and including regular inspection at the manufacturer's premises. or the product has been batch-tested.

PSB also operates the PSB ISO 9000 Certification Scheme which is a third party quality system certification of manufacturing processes and services to the relevant part of the SS ISO 9000 series of standards on quality systems_ The scheme confers recognition to companies which have properly designed and implemented quality systems. It enables companies to Cain greater international recognition thereby facilitating access to overseas markets. it also helps companies to reduce reject costs and improve quality and productivity. Certified companies are entitled to use the PSB ISO 9000 symbol as shown in Figure 3 in their marketing programme including letterheads, advertisements and other promotional materials.

in addition, PSB also operates the PSB ISO 14000 (Environmental Management System) Certification Scheme which is a third party certification of environmental management systems to ISO 14001 environmental management system standard. The scheme provides an independent and impartial assessment with a view for continuous improvement in environmental performance. Certified companies are entitled to use the PSB ISO 14000 Mark as shown in Figure 4 in their promotional materials.

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