

Revised for 2014

Quality Management Systems Guide

Guiding your organization to excellence in all the dimensions important to your business and customers

Tim Landerville, President,
Isocert Solutions, LLC

New for 2014

Risk, Software,
and an
overview of
the proposed
changes to
ISO9001 to be
released
September
2015





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Quality Management Systems Guide

1. INTRODUCTION

Many challenges confront companies that are involved in the product/services delivery industry. Periods of tremendous growth may be interrupted by economic downturn. Capital assets are aging and costs to maintain and replace them are increasing. Changing workforce demographics and the availability of resources are affecting the planning and execution of certain projects.

These challenges call for a renewed focus on proactively managing quality, and demand an increased awareness of the impact an effective Quality Management System (QMS) can have on the success of an organization.

Whether you are a young quality manager just starting out or a veteran quality management professional it is important to learn and be aware of the basics of quality and the ISO System (International Organization for Standardization).

Quality Management (QM) information from past research is extensive; however, advancements in technologies, tools, and processes have changed how quality management systems (QM systems) are currently being used.

Furthermore, quality management practices once thought to be valuable may have lost some of their effectiveness. Therefore, an understanding of what constitutes a modern Quality Management System (QMS) is not only required, it is essential.



2. HOW DID IT ALL START?

From the time the ISO series of quality management standards were released in 1987, there have been concerns that certification of a Quality Management System did not necessarily assure stakeholders that conforming products or services would be delivered to the customer on time. To a large extent these concerns continue today. In 1995 QS-9000 was introduced with the thought that things would get better. This was followed by other sector-specific standards, TL 9000 for Telecommunications, AS9100 for Aerospace, and ISO/TS 16949 replaced QS-9000. All of these had the common goal of delivering high quality products or services on time, thereby achieving customer satisfaction. What many organizations miss or do not understand is how they can realize true value from their certification.



[Walter A. Shewhart](#) made a major step in the evolution towards quality management by creating a method for quality control for production, using statistical methods, first proposed in 1924. This became the foundation for his ongoing work on statistical quality control.



[W. Edwards Deming](#) later applied statistical process control methods in the United States during World War II, thereby successfully improving quality in the manufacture of munitions and other strategically important products.

Quality leadership from a national perspective has changed over the past five to six decades. After the Second World War, Japan decided to make quality improvement a national imperative as part of rebuilding their economy, and sought the help of [Shewhart](#), [Deming](#) and [Juran](#), amongst others.

[W. Edwards Deming](#) championed Shewhart's ideas in Japan from 1950 onwards. He is probably best known for his management philosophy establishing quality, productivity, and competitive position. He formulated [14 points](#) of attention for managers, which are a high level abstraction of many of his deep insights. They should be interpreted by learning and understanding the deeper insights.

These [14 points](#) include key concepts such as:

- Breaking down barriers between departments
- Management should learn their responsibilities and take on leadership
- Supervision should be to help people and machines and gadgets to do a better job
- Improve constantly and forever the system of production and service
- Institute a vigorous program of education and self-improvement

[Philip Crosby, the Guru of Quality Management](#), was a legend in the discipline of quality. A noted quality professional, consultant, and author, he is widely recognized for promoting the concept of "zero defects" and for defining quality as conformance to requirements.

Some of his concepts that set the stage for the current ISO family of standards include quality as conformity to certain specifications set forth by management and not some vague concept of "goodness." These specifications are not arbitrary either; they must be set according to customer needs and wants.

Four Absolutes of Quality Management

1. Quality is defined as conformance to requirements, not as 'goodness' or 'elegance'.
2. The system for causing quality is prevention, not appraisal.
3. The performance standard must be Zero Defects, not "that's close enough".
4. The measurement of quality is the Price of Nonconformance, not indices.

3. DEFINING QUALITY MANAGEMENT

A quality management system (QMS) can be defined as the organizational structure, procedures, processes and resources needed to implement quality management. - Wikipedia

In other words, a quality management system should be viewed as a set of interrelated or interacting components that organizations use to direct and control how quality policies and procedures are implemented and quality objectives are achieved.



2. **Industry-wide:** Global solutions to satisfy industries and customers worldwide.
3. **Voluntary:** International standardization is market-driven and therefore based on voluntary involvement of all interests in the market-place.

Standards are revised periodically to remain relevant and current with advancements in technology and global business conditions.

5. THE ISO FAMILY

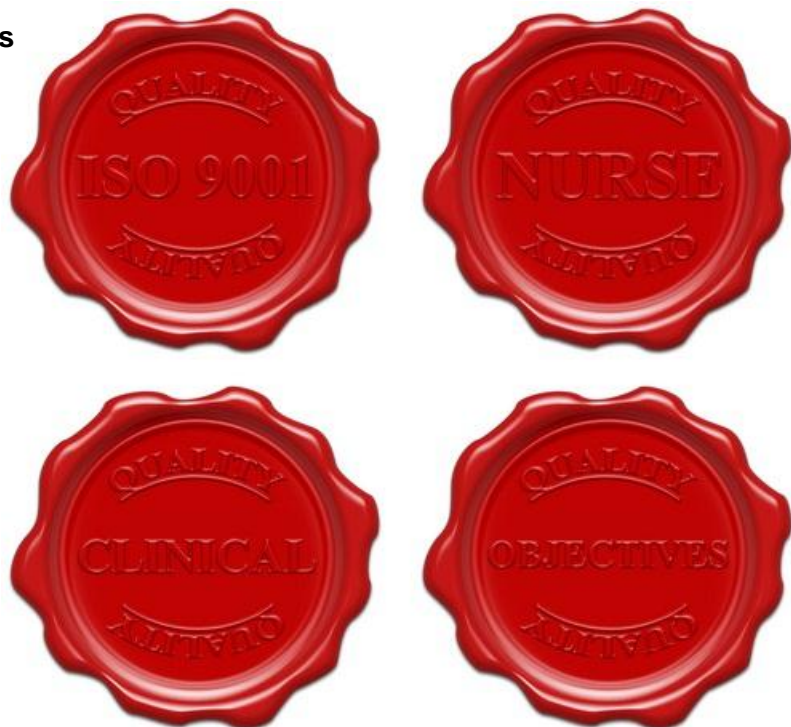
The International Organization for Standardization develops and publishes International Standards and it defines a standard as follows:

“A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.”

The focus of the ISO International Standards is to make sure that products and services are safe, reliable and of good quality. In the business environment these standards are strategic tools that help to reduce costs by minimizing waste and errors and increasing productivity. It helps companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.

Development of ISO Standards

An ISO standard is developed by a panel of experts, within a technical committee. Once the need for a standard has been established, these experts meet to discuss and negotiate a draft standard. As soon as a draft has been developed it is shared with ISO's members who are asked to comment and vote on it. If a consensus is reached the draft becomes an ISO standard, if not it goes back to the technical committee for further edits.



The key principles in developing a new standard are:

1. ISO standards respond to a need in the market
2. ISO standards are based on global expert opinion
3. ISO standards are developed through a multi-stakeholder process
4. ISO standards are based on a consensus

ISO has a number of management system standards, each focusing on different issues affecting global business.

Some of the well-known ones are:

- **ISO 50001**
 - Energy Management
- **ISO 9001**
 - Quality Management
- **ISO 14000**
 - Environmental Management
- **ISO 22000**
 - Food Safety Management



6. QUALITY MANAGEMENT SYSTEM MISSION STATEMENT

To determine the objectives and quality policy, the criteria of the ISO 9001 standards requires companies to establish a QMS Quality Policy that will enable them to manage, control and improve processes in their organization in order to assure that services and products meet the requirements of the customer. For example:

Our Values:

We uphold the following values:

- Confidentiality
- Discretion
- Trust
- Good judgment
- Honesty

Our customers: We provide our customers with the best service possible based on the understanding that we need their long-term loyalty and support to flourish.

Our relationships: We create mutually beneficial long-term relationships with our people, customers and suppliers.

Our people: We treat our people with dignity and respect and are committed to help them reach their full potential through development and training. We also encourage them to participate in decisions that influence their daily working lives.

Innovation/creativity: We encourage our people, customers and suppliers to solve problems through innovation and creativity and to seize opportunities.

Quality: We strive for an environment where quality is of paramount importance.



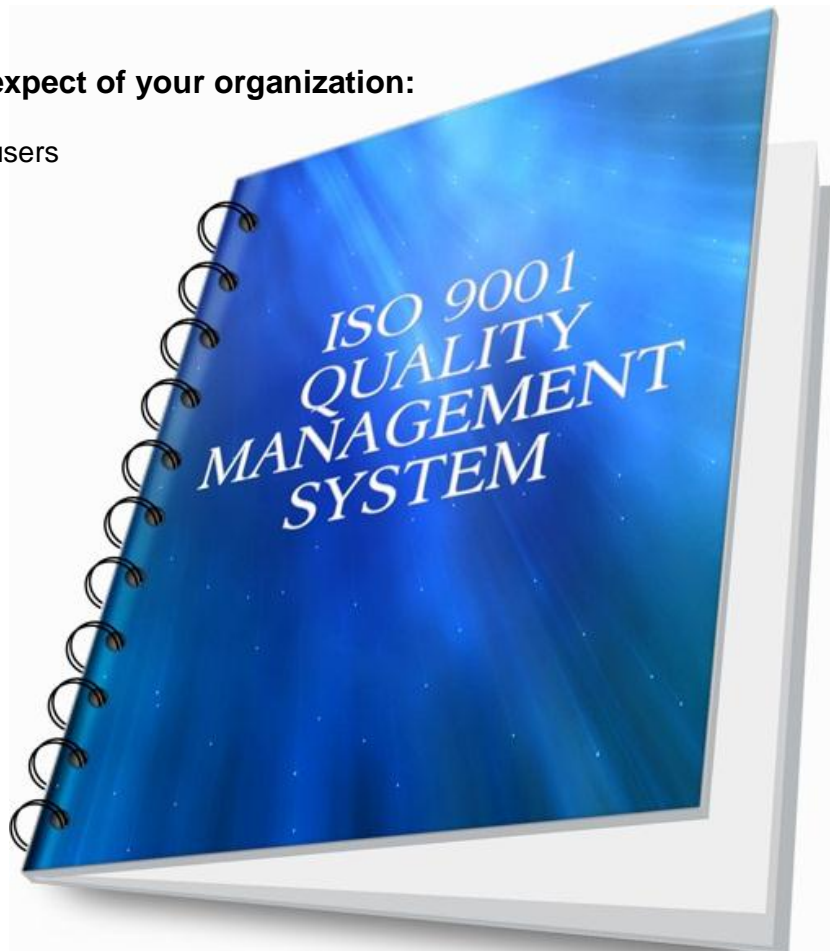
7. IMPLEMENTING YOUR QUALITY MANAGEMENT SYSTEM

1. Identify the goals your organization wants to achieve:

- 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. Identify what others expect of your organization:

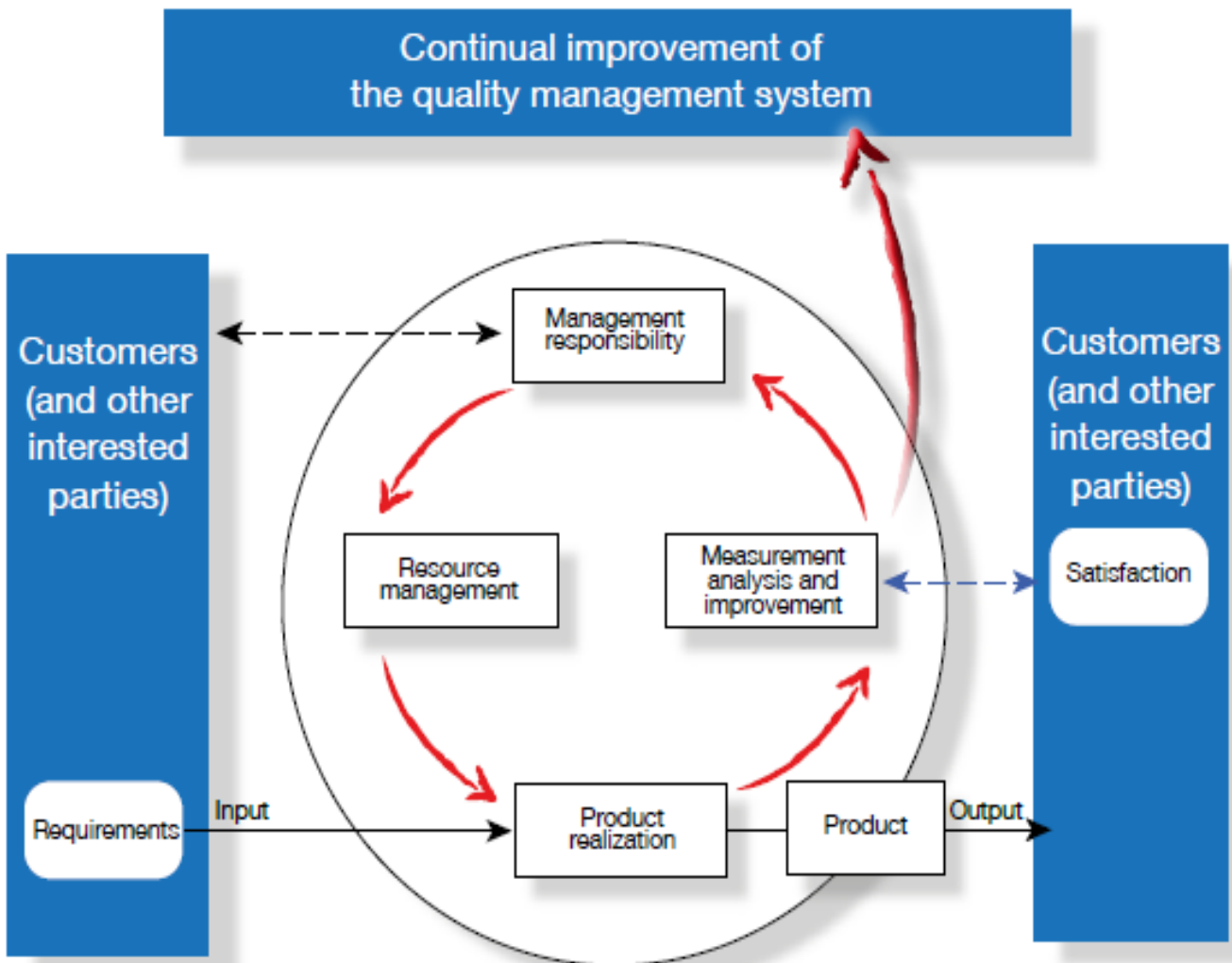
- Customers and end users
- Employees
- Suppliers
- Shareholders
- Society



8. CORE STANDARDS

There are five sections in the standard that specify activities that need to be considered when your organization implements a Quality Management System. The combined key factors are:

1. Overall requirements for the Quality Management System and documentation
2. Leadership Management responsibility, focus, policy, planning and objectives
3. Resource management and allocation
4. Product realization and process management
5. Measurement, monitoring, analysis and improvement



Source : www.iso.org - the ISO 9000 process approach

9. RISK MANAGEMENT IN YOUR ORGANIZATION

Risk management has become more and more critical in today's business environment. You can no longer count on taking measures to correct a problem after it happens. In today's instant information technology world the damage to your company's reputation as a supplier of quality products or services can be damaged beyond repair before you can take corrective action. *What can you do to reduce this potential? Risk Management Planning!*

The goal of risk management is to protect organizations from being vulnerable.

Risk Management process begins with identifying, assessing and prioritizing potential risks. The next step in the process is to take action to minimize or eliminate the impact of negative events.

Examples of common types of risk that management can control the impact of are:

- Accidents in the workplace
- Natural disasters such as fire, tornadoes, floods and earthquakes
- Supply chain disruption
- Legal Risks include fraud, theft, sexual harassment
- Financial uncertainty, project failure, credit risks, data storage and security





There are as many ways to eliminate or mitigate risk as there are risk factors. Here are 4 main approaches:

- Do nothing - accept consequences
- Insure - Transfer risk to another party
- Close down risky area of organization
- Take action to prevent risk situation

Every company should implement a risk management plan, it is the responsible path to take in maintaining a successful organization that protects its people, financial integrity and physical assets.

10. USING SOFTWARE TO IMPLEMENT YOUR QUALITY SYSTEM

What is the benefit of using an electronic system to implement and maintain your quality management system? In the past a typical quality Management System was located in large binders located throughout the organization. This method while it worked was a nightmare to control. Controlled documents had to be manually recalled, revised, reprinted approval signatures on every copy obtained and distributed to every location every time there was a revision to a document. Then there are the forms for collecting data and recording information, where are these located? This is quite a lot of paper to manage.

Today's electronic environment allows for all Quality Management System Documents, forms, logs and records to be located in one place accessible by all who need them with no risk of obsolete documents being used in the workplace.

You can link documents to their associated forms and logs, significantly increasing efficiency, enhancing productivity and effectiveness of your Quality Management System.

Isocert SE is an example of QMS software – [follow this link for a free Sample](#).



Welcome to **SAMPLE** Version of
ISOCERT SE

Quality Policy

[Insert Your Company name here](#) will
provide world class customer service

11. THE EIGHT PRINCIPLES OF QUALITY MANAGEMENT

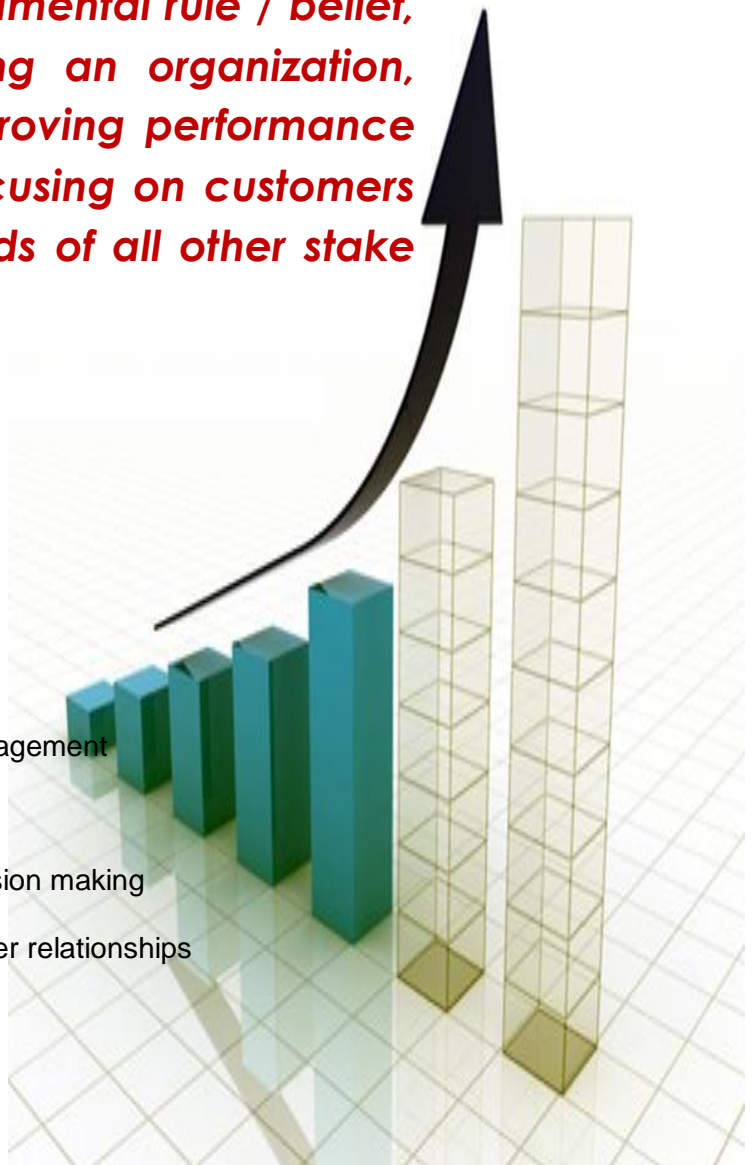
Since Quality Management is becoming increasingly important to the leadership and management of all organizations it is necessary for us to identify Quality Management as a distinctive discipline of management and lay down universally understood and accepted rules for this discipline.

The ISO technical committee working on the ISO 9000 standards had published a document detailing the quality management principles and application guidelines and defines a Quality Management Principle as follows:

"A quality management principle is a comprehensive and fundamental rule / belief, for leading and operating an organization, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all other stake holders".

Quality Management Principles:

- 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



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.

The key steps in applying a Customer Focus are:

- i. Understand your customers' needs and expectations for products, delivery, price, dependability, etc.
- ii. Ensure a balanced approach among customers and other stake holders (owners, partners, people, suppliers, local communities and society at large) needs and expectations.
- iii. Communicate these needs and expectations throughout the organization.
- iv. Measure customer satisfaction and act on results.
- v. Manage customer relationships.



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.

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.

The key steps in applying the Leadership principle are:

- i. Be proactive and lead by example.
- ii. Understand and respond to changes in the external environment.
- iii. Consider the needs of all stake holders including customers, owners, people, suppliers, local communities and society at large.
- iv. Establish a clear vision of the organization's future.
- v. Establish shared values and ethical role models at all levels of the organization.
- vi. Build trust and eliminate fear.
- vii. Provide people with the required resources and freedom to act with responsibility and accountability.
- viii. Inspire, encourage and recognize people's contributions.
- ix. Promote open and honest communication.
- x. Educate, train and coach people.
- xi. Set challenging goals and targets, and
- xii. Implement a strategy to achieve these goals and targets.



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.

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.

The key steps in applying the Involvement of People principle are:

- i. Accept ownership and responsibility to solve problems.
- ii. Actively seek opportunities to make improvements and enhance competencies, knowledge and experience.
- iii. Freely share knowledge & experience in teams.
- iv. Focus on the creation of value for customers.
- v. Be innovative in furthering the organization's objectives.
- vi. Improve the way of representing the organization to customers, local communities and society at large.
- vii. Help people derive satisfaction from their work.
- viii. Make people enthusiastic and proud to be part of the organization.



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.

PRINCIPLE 4: PROCESS APPROACH

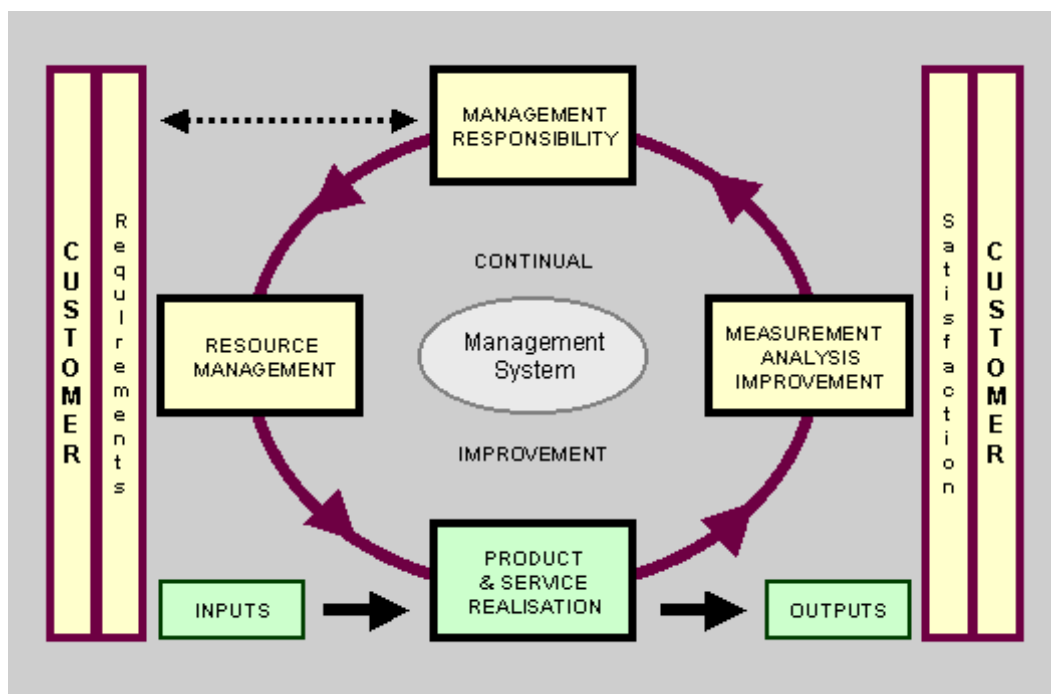
A desired result is achieved more efficiently when activities and related resources are managed as a process.

The key steps in applying the Process Approach are:

- i. Define the process to achieve the desired result.
- ii. Identify and measure the inputs and outputs of the process.
- iii. Identify the interfaces of the process with the functions of the organization.
- iv. Evaluate possible risks, consequences and impacts of processes on customers, suppliers and other stake holders of the process.
- v. Establish clear responsibility, authority, and accountability for managing the process.
- vi. Identify internal and external customers, suppliers and other stake holders of the process, and
- vii. When designing processes, consider process steps, activities, flows, control measures, training needs, equipment, methods, information, materials and other resources to achieve the desired result.

Key benefits:

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





PRINCIPLE 5: SYSTEM APPROACH TO MANAGEMENT

Identifying, understanding and managing a system of interrelated processes for a given objective improve the organization's effectiveness and efficiency. Using a systems approach to management involves identifying all of an organization's processes as well as their interdependence and managing the processes as a complete system.

Key steps in applying the System Approach to Management are:

- i. Define the system by identifying or developing the processes that affect a given objective.
- ii. Structure the system to achieve the objective in the most efficient way.
- iii. Understand the interdependencies among the processes of the system.
- iv. Continually improve the system through measurement and evaluation, and
- v. Estimate the resource requirements and establish resource constraints prior to action.

Key benefits:

- Identifies all of the steps required to conduct business and meet the customer's requirements.
- Identifies the sources of variation that can produce inefficiencies.
- Provides an effective and efficient means of achieving the companies' goals while providing a better understanding to the employees of how to achieve common objectives.

PRINCIPLE 6: CONTINUAL IMPROVEMENT

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

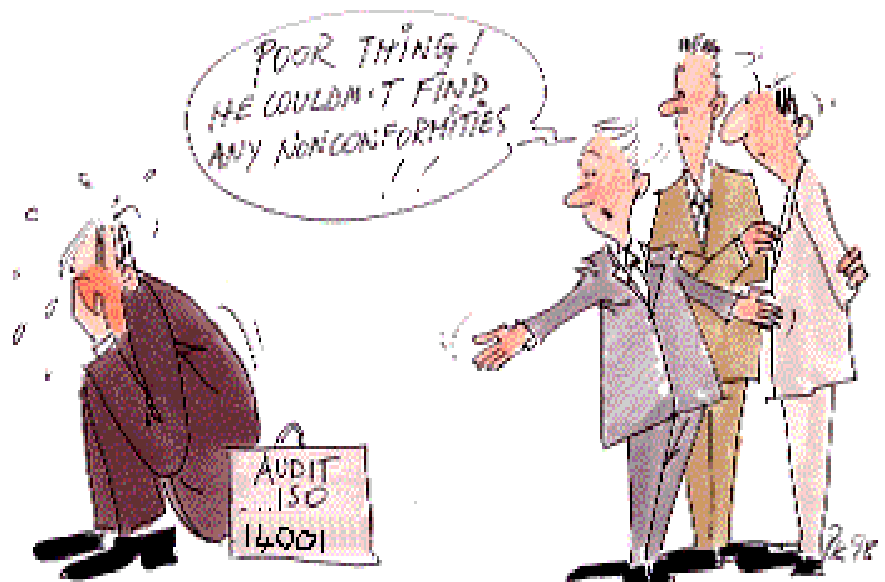
Key steps in applying the Continual Improvement principle are:

- i. Make continual improvement of products, processes and systems an objective for every individual in the organization.
- ii. Apply the basic improvement concepts of incremental improvement and breakthrough improvement.
- iii. Use periodic assessments against established criteria of excellence to identify areas for potential improvement.
- iv. Continually improve the efficiency and effectiveness of all processes.

- v. Promote prevention based activities.
- vi. Provide every member of the organization with appropriate education and training, on the methods and tools of continual improvement such as the Plan-Do-Check-Act cycle, problem solving, process re-engineering, and process innovation.
- vii. Establish measures and goals to guide and track improvements.
- viii. Recognize improvements.

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.



PRINCIPLE 7: FACTUAL APPROACH TO DECISION MAKING

The Factual approach to decision making principle simply states that "Effective decisions are based on the analysis of data and information."

The key steps in applying the Factual Approach to Decision Making are:

- i. Take measurements and collect data and information relevant to the objective.
- ii. Ensure that the data and information are sufficiently accurate, reliable and accessible.
- iii. Analyze the data and information using valid methods.
- iv. Understand the value of appropriate statistical techniques, and
- v. Make decisions and take action based on the results of logical analysis balanced with experience and intuition.



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.

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.

Steps in the application of this principle are:

- i. Identify and select key suppliers.
- ii. Establish supplier relationships that balance short-term gains with long-term considerations for the organization and society at large.
- iii. Create clear and open communications.
- iv. Initiate joint development and improvement of products and processes.
- v. Jointly establish a clear understanding of customers' needs.
- vi. Share information and future plans, and
- vii. Recognize supplier improvements and achievements.



Key benefits:

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

12. CONTINUOUS IMPROVEMENT PLAN

CIPs, also known as continuous quality improvement plans, are programs designed to review specific situations and identify strategies for enhancing or improving all related factors.

A continuous improvement process can be employed to evaluate policies and procedures in just about any business setting.

The notion is to make something that is already good even better, thus benefiting the company in general.



W. Edwards Deming, saw it as part of the 'system' whereby feedback from the process and customer were evaluated against organizational goals. **The fact that it can be called a management process does not mean that it needs to be executed by 'management'**; but rather merely that it makes decisions about the implementation of the delivery process and the design of the delivery process itself.

✚ *The core principle of CIP is the (self) reflection of processes. (Feedback)*

✚ *The purpose of CIP is the identification, reduction, and elimination of suboptimal processes. (Efficiency)*

✚ *The emphasis of CIP is on incremental, continual steps rather than giant leaps. (Evolution)*

The whole QMS is owner driven.

Ongoing control is of importance in the QMS network

Process linkage and interaction is essential



- ACT** – Implementation of improvement
- PLAN** – Identification of sequence, interaction criteria and methods
- DO** – Implementation of the planning
- CHECK** – Monitoring, measurement and analysis

13. THE AUDIT

A Quality Audit is the process of systematically examining the quality management system of an organization and is usually carried out by an internal or external quality auditor or an audit team.

Quality audits are typically performed at predefined time intervals and ensure that an organization has clearly defined internal system monitoring procedures linked to effective action - audits examine a Quality Management System for correct implementation and adequacy. This can help determine if the organization complies with the defined quality system processes and can involve procedural or results-based assessment criteria.

For the benefit of the organization, quality auditing should not only report non-conformances and corrective actions, but also highlight areas of good practice. In this way other departments may share information and amend their working practices as a result, also contributing to continual improvement.

The Audit Process consists of four stages:

1. **Preparation** – assign auditors, agree on audit program, gather and review all documentation and develop a checklist.
2. **Performance** – open meeting, conduct audit, audit team meeting and closing of the meeting.
3. **Reporting** – within fourteen days of the completion of an audit, an audit report should be completed and issued to the auditee.
4. **Follow-up** – non-conformances identified must be rectified.





14. THE CERTIFICATION

Certification is the process whereby an independent and accredited organization certifies that a third party complies with specific requirements. Wikipedia describes it as follows:

“ISO does not certify organizations itself. Numerous certification bodies exist, which audit organizations and, upon success, issue ISO 9001 compliance certificates. Although commonly referred to as "ISO 9000" certification, the actual standard to which an organization's quality management system can be certified is ISO 9001:2008. Many countries have formed accreditation bodies to authorize ("accredit") the certification bodies. Both the accreditation bodies and the certification bodies charge fees for their services. The various accreditation bodies have mutual agreements with each other to ensure that certificates issued by one of the Accredited Certification Bodies (CB) are accepted worldwide. Certification bodies themselves operate under another quality standard, ISO/IEC 17021,¹ while accreditation bodies operate under ISO/IEC 17011.”

The three main Certification Schemes are:-

1. System Certification
2. Product/Service Certification
3. Consignment Inspection

15. THE FUTURE

In order for the ISO family of standards to maintain its efficiency, the ISO standards are reviewed at regular intervals to benefit from new developments in the quality management arena and also from user and supplier feedback.

ISO/TC 176 monitors the use of the standards to determine how they can be improved to meet user needs and expectations when the next revisions are due. They comprise of experts from businesses and other organizations around the world. All ISO standards are reviewed regularly for relevancy; changes are made when there is an established need to improve the standard.

Based on input from the user community, ISO/TC 176 continues to evaluate and adopt new concepts in the field of quality management for incorporation into ISO standards. This can include specialised segment initiatives and supporting documents within the ISO family of standards. Most ISO technical committees recognize the structure of ISO 9001 when new management systems standards are developed for other or specific purposes.



ISO9001:2015 WHAT IS COMING?

While the revision to the ISO Quality Standard is still out for comment and will not be published until 2015 it is possible to see from the committee draft the direction the standard is going.

- The exclusions clause has been omitted due to the fact the committee is expressing the requirements differently than in past revisions making the exclusions clause redundant.
- ISO 9001 is seeking to become more generic and applicable to companies providing any type of product and greater acceptance in the area of service providers' service. To accomplish this the use of "goods and services" is replacing "product"
- ISO 9001 specifies requirements "essential to the adoption of the process approach" now required in clause 4.4
- ISO 9001 is changing its high level structure to bring all Management System standards into harmony, where in the past the basic structure of each standard differed from the next causing confusion and difficulties for organizations and assessors alike.
 - The draft standard is reorganized currently listing 10 sections replacing the current version with 8.
 - Section 4 now "Context of the Organization" replaces "General Requirements".
 - Section 5 now called "Leadership" replaces "Management Responsibilities".
 - Management Review and Internal Audit are now placed in section 9 Performance Evaluation.
- Preventive Action is no longer in the standard but Risk Management has been added to section 6 - Planning.
- "Documented Information" replaces the requirement for documented procedures and records, this appears to address this modern electronic age way of delivering and recording information.

A "Revised QMS Guide" will be made available as soon as the new ISO Standards are made available in 2015.

16. SUMMARY

ISO's pledge to sustaining the ISO 9001 momentum through reviews, improvement and streamlining of the standards guarantees that an organization's confidence and involvement in ISO 9001 today will continue to provide effective management solutions well into the future.



Author: Tim Landerville, CEO Isocert Solutions LLC

Isocert Solutions was founded in 1990 in Sonoma County California by partner Tim Landerville, Certified Lead Auditor, and has grown steadily since its inception. It maintains its corporate office in Santa Rosa, California and others throughout the United States.

The company specializes in Enterprise-class software that is made for scalability, high performance, quality management and robustness. Their software provides businesses with logic support functionality, enabling enterprises to improve product quality, services and productivity while providing efficiency gains. For more information please see: <http://isocertsolutions.com/> or call (707) 570-5669 to discuss how to become ISO 9001 certified.

