ISO 9000 Basics

http://www.iso.org
ISO Standards
What is ISO?

- The International Organization for Standardization (ISO) is an international standard-setting body composed of representatives from various national standards bodies (NSBs). Founded on 23 February 1947, the organization produces world-wide industrial and commercial standards and is the world's largest developer of standards.

- ISO defines itself as a non-governmental organization (NGO), its ability to set standards that often become law, either through treaties or national standards, makes it more powerful than most NGOs. In practice, the ISO acts as a consortium with strong links to governments. As of fall 2006, there are 158 members, each of which represents one country.
ISO Standards
Some ISO Members - NSBs

- **USA**: ANSI – American National Standards Institute
- **United Kingdom**: BSI – British Standards Institution
- **Japan**: JISC – Japan Industrial Standards Committee
- **Canada**: SCC – Standards Council of Canada
- **Mexico**: DGN – Dirección General de Normas
- **China**: SAC – Standardization Administration of China
- **India**: BIS – Bureau of Indian Standards
- **Israel**: SII – Standards Institution of Israel
- **Iran, Islamic Republic of**: ISIRI – Institute of Standards and Industrial Research of Iran
ISO Standards
What are they?

- ISO standards also have important economic and social repercussions:
  - when the business or industry sectors conform to International Standards, a sector or industry-wide standardization can be said to exist
  - this is achieved through consensus agreements between national delegations representing all the economic stakeholders concerned - suppliers, users, government regulators and other interest groups, such as consumers

- The vast majority of ISO standards are highly specific to a particular product, material, or process. However, two standards that have earned a worldwide reputation as "generic management system standards" are the ISO 9000 and ISO 14000 families.
ISO Standards
What are they?

- ISO 9000 is a family of standards for a quality management system (QMS)

- ISO 14000 is a family of standards for an environmental management system (EMS)

- "Management system" refers to the organization's structure for managing its processes or activities that transform inputs of resources into a product or service which meet the organization's objectives, such as satisfying the customer's quality requirements, complying to regulations, or meeting environmental objectives.

- The ISO 9000 and ISO 14000 families are among ISO's most widely known standards. ISO 9000 and ISO 14000 standards are implemented by some 887,770 organizations in 161 countries.
ISO 9000 and ISO 14000
What are they?

- Both are maintained by ISO, the International Organization for Standardization and is administered by accreditation and certification bodies.

- "Generic" means that the same standards can be applied:
  - to any organization, large or small, whatever its product
  - including whether its "product" is actually a service,
  - in any sector of activity, and
  - whether it is a business enterprise, a public administration, or a government department.

- "Generic" also signifies that no matter what the organization's scope of activity, if it wants to establish a quality management system or an environmental management system, then such a system has a number of essential features for which the relevant standards of the ISO 9000 or ISO 14000 families provide the requirements.
Some Industry/Sector-specific QMS Standards

- QS 9000 – Big 3 Automotive
- ISO/TS 16949 – Int’l Automotive
- AS 9100 – Aerospace
- ISO/IEC 17025 - Testing & Calibration Labs
- TL 9000 – Telecommunications
- FS 9000 – Financial Services
- AG 9000 - Agriculture
ISO 9000
What is it?

- The ISO 9000 family is primarily concerned with "quality management". This means what the organization does to fulfil:
  - the customer's quality requirements, and
  - applicable regulatory requirements, while aiming to
  - enhance customer satisfaction, and
  - achieve continual improvement of its performance in pursuit of these objectives

- The Latest standard for certification of QMS is:
  ISO 9001-2000
  - replaced the ISO 9000 series of 1994
  - emphasizes process over procedures
  - focuses on customer satisfaction over compliance
History of ISO 9000

• ISO 9000:1987 - with the rise of international trade in the 1980's there was a need for some kind of internationally recognized quality system. To that end BS5750 (British Standard) was given a face-lift and was issued as an ISO standard.

Note: One of the rules of ISO is that they review all their standards every five years.

• ISO 9000: 1994 Series - the first time ISO 9000 required a quality manual; contained 20 elements for a QMS; useful but muddled.


ISO 9002 and ISO 9003 were made obsolete. All companies will comply with ISO 9001. Some exclusions are permitted, but the exclusions are limited to the Product Realization requirements (ISO 9001:2000 Section 7). Exclusions are only permitted where an element of Section 7 is genuinely not relevant to the company.
COMPARISON OF 1994 WITH 2000 APPROACH

Procedures
1. are driven by completion of a task
2. are implemented
3. are steps completed by different people in different departments with different objectives
4. are discontinuous
5. focus on satisfying the rules
6. define the sequence of steps to execute a task
7. may be used to process information
8. exist – they are static

Processes
1. are driven by achievement of a desired result
2. are operated
3. stages are completed by different people within the organization
4. flow to a conclusion
5. focus on satisfying interested parties
6. transform inputs into outputs through the use of resources
7. information is processed through the use of a procedure
8. behave – they are dynamic
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 product 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
ISO 9000 Basics

The Family of Standards


"The greatest value is obtained when you use the entire family of standards in an integrated manner. It is suggested that, beginning with ISO 9000:2000, you adopt ISO 9001:2000 to achieve a first level of performance. The practices described in ISO 9004:2000 may then be implemented to make your quality management system increasingly effective in achieving your own business goals."

- source: www.iso.org
ISO 9000 Basics

- ISO 9001 certified or registered - A company or organization that has been independently audited and certified to be in conformance with ISO 9001 may publicly state that it is certified or registered.

- Certification to an ISO 9000 standard does not guarantee the compliance (and therefore the quality) of end products and services; rather, it certifies that consistent business processes are being applied.

- Although the standards originated in manufacturing, they are now employed across a wide range of other types of organizations, including colleges and universities. A "product", in ISO vocabulary, can mean a physical object, or service, or software. In fact, according to ISO in 2004, "service sectors now account by far for the highest number of ISO 9001:2000 certificates - about 31% of the total..."

  - source: the ISO Survey 2004

1. Identify the goals you want to achieve
2. Identify what others expect of you
3. Obtain information about the ISO 9000 family
4. Apply the ISO 9000 family of standards to your management system
5. Obtain guidance on specific topics within the quality management system
6. Establish your current status, determine the gaps between your quality management system and the requirements of ISO 9001:2000 – “GAP Analysis”
7. Determine the processes that are needed to supply products to your customers
8. Develop a plan to close the gaps in step 6 & to develop the processes in step 7
9. Carry out your plan
10. Undergo periodic internal assessment
11. Do you need to demonstrate conformance? If yes, go to step 12; If no, go to step 13
12. Undergo independent audit – i.e. Registration/Certification
13. Continue to improve your business
Why get ISO 9001:2000 Certified/Registered?

- To meet Customer Expectations
- To compete in the Global Market
- To reduce costs by continually improving our products and processes by measuring our performance to the globally adopted ISO 9001 Standard
- Mutual Recognition - International Standards are the technical means by which political trade agreements can be put into practice.
- Improve Supplier Partnerships - the worldwide compatibility of technology which is achieved when products and services are based on International Standards brings us an increasingly wide choice of offers - we also benefit from the effects of competition among suppliers.
Accreditation and Certification/Registration Bodies

- The ANSI-ASQ National Accreditation Board is the U.S. accreditation body for management systems. ANAB accredits certification bodies (CBs) for ISO 9001 quality management systems (QMS) and ISO 14001 environmental management systems (EMS), as well as a number of industry-specific requirements.

Note: The Registrar Accreditation Board (RAB) ceased operations as of January 1, 2005. RAB's accreditation programs for management systems certification bodies are now operated by the ANSI-ASQ National Accreditation Board.

- Some popular Certification Bodies (a.k.a. Registrars):
  - BVQI (Bureau Veritas Certification), NSF International Strategic Registrations, UL (Underwriters Laboratory), DNV (Det Norske Veritas), TUV-America, NQA (National Quality Assurance), LRQA (Lloyd's Register Quality Assurance)…
ISO 9001:2000 QMS Requirements

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:

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

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

ISO 9004:2000 Guidelines for Performance Improvements

4 Quality management system

4.1 Managing systems and processes

Leading and operating an organization successfully requires managing it in a systematic and visible manner.

Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organization's performance by considering the needs of interested parties. Managing an organization includes quality management, among other management disciplines.

Top management should establish a customer-oriented organization...

Examples of activities to establish a customer-oriented organization include:
- defining and promoting processes that lead to improved organizational performance,
- acquiring and using process data and information on a continuing basis,
- directing progress towards continual improvement, and
- using suitable methods to evaluate process improvement, such as self-assessments and management review.
Both A Process and System Approach

Process Approach - For an organization to function effectively it has to identify and manage a number of linked activities.

All activities use resources (e.g. people, plant, equipment) to transform a process input into a process output. The output of one process is often the input of the next process. The Quality Management System (QMS) should be regarded as an inclusive system that describes our business and provides us with useful information (*8.4), rather than some strange, "alien" set of books that the Quality Manager keeps exclusively for the benefit of the Certification Body.

System Approach - By identifying, understanding and managing the interrelated processes, the effectiveness and efficiency of the QMS can be assessed.

"Effectiveness" means that the QMS works and achieves its objectives. "Efficient" means that the QMS uses minimum resources. For effective decisions to be made the *information generated by the QMS must be analyzed.

*Analysis of data - Clause 8.4.
Value of "Conformance"

ISO standards make a positive difference, not just to engineers and manufacturers for whom they solve basic problems in production and distribution, but to society as a whole.

ISO standards contribute to making the development, manufacturing and supply of products and services more efficient, safer and cleaner.

They make trade and technology transfer between countries easier and fairer. They provide governments with a technical base for health, safety and environmental legislation.

ISO standards also serve to safeguard consumers, and users in general, of products and services - as well as to make their lives simpler.

When things go well - for example, when systems, machinery and devices work well and safely - it is because they conform to standards.

And the organization responsible for many thousands of the standards which benefit society worldwide is ISO.
Conformance vs. Compliance

- Compliance: The state of an organization that meets prescribed specifications, contract terms, regulations or standards.
  e.g. XYZ Co. is ISO 9000-compliant

- Conformance: An affirmative indication or judgment that a product or service has met the requirements of a relevant specification, contract or regulation.
  e.g. XYZ Co.'s design and development process conforms to ISO 9000 requirements

- source www.asq.org
Quality Management Principles

The eight quality management principles on which the quality management system standards of the revised ISO 9000:2000 series are based 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.

These principles can be used by senior management as a framework to guide their organizations towards improved 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
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.
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.
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.
Principle 4 - Process Approach

A desired result is achieved more efficiently when activities and related resources are managed as a process. *(similar to the concept of statistical thinking)*

Key benefits:

- Lower costs and shorter cycle times through effective use of resources.
- Improved, consistent and predictable results.
- Focused and prioritized improvement opportunities.
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.
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.
Principle 7 - Factual Approach to Decision Making

Effectual 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.
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.
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What do you need to know to pass an ISO Audit?

1. The Quality Policy.

2. The goals and objectives of the Organization – and your contribution to meet the company’s goals and objective.

3. Know your process and responsibilities.

4. Know how to answer auditor’s questions.
The Quality Policy

Quality Policy @ Motorola

“Motorola is committed to delight customers* by serving them to their highest level of expectations and by delivering products and services of the highest quality on time every time. This will be achieved in partnership with customers, suppliers and stakeholders, using leading systems, technologies and methods* and by fully engaging employees in a culture of continuous improvement*.”

*Note: three requirements of ISO are:

1. Customer Focus
2. Continual Improvement
3. Maintain effective systems and processes
Know your process and responsibilities.

Your process may or may not be documented. If it is documented and you offer this information to the auditor, you will be audited to that document.

Your process may be mapped in a process flowchart or other type of diagram.

Your process may be available on the company’s intranet or in an electronic document management system.
Know how to answer auditor’s questions.

Answer honestly – you have nothing to fear or hide if you know your process.

Answer only the question that is asked – don’t offer information that is not in the realm of your responsibility.

You should have a process document or diagram on hand - use it.

You can go to your portal and walk the auditor through the process.
What needs to be documented?

The following 6 procedures are required to be documented by ISO 9001:

They are the only mandatory procedures identified as required by ISO 9001.

4.2.3 Document control procedure
4.2.4 Control of records procedure
8.2.2 Internal audit procedure
8.3 Control of non-conformance procedure
8.5.2 Corrective action procedure
8.5.3 Preventive action procedure

Requirements for other documents: the minimum you feel are necessary to demonstrate control.
What is a procedure?

The ISO9000:2000 definition of a procedure is:

"Specified way to carry out an activity or a process" - may be documented or not. This does not necessarily mean one of the 6 "Required Procedures" specified by ISO9001:2000.

We all can map our processes on a process turtle or flowchart.

PROCEDURE*
("Specified way to carry out an activity or a process" - may be documented or not)

PROCESS
("Set of interrelated or interacting activities")

MONITORING AND MEASUREMENT OPPORTUNITIES
(Before, during and after the process)

EFFECTIVENESS OF PROCESS = Ability to achieve desired results (Focus of ISO 9001:2000)

EFFECTIVENESS OF PROCESS = Results achieved vs resources used (Focus of ISO 9004:2000)

PRODUCT
("Result of a process")

* Note – This is the definition of "procedure" given in ISO 9000:2000.
This does not necessarily mean one of the 6 "documented procedures" required by ISO 9001:2000.
Alternatives to Documents

- Process Maps and flowcharts
- Templates on the intranet (portals) or shared drives
- Hard copy instructions in local binders – e.g. OJT
0. Take notes of significant steps, work products, templates, verification, validation and handoff activities so you can assure that all people do it the same way.

0. You must be competent to evaluate processes, failure modes, trend analyses, review records, etc.

0. The objective evidence of effective and efficient process should be measured and recorded. Measured outputs can include yield, specs, budget, schedule, etc.