ISO 9000

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All figures are taken from(unless otherwise mentioned)
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ISO

- The International Standards Organization (founded in 1946 in Geneva, Switzerland), known as ISO, has developed a series of standards for quality systems.
- The first standards were issued in 1987.
  - The current version of the standard is known as the ISO 9000 series.
- It is a generic standard, broadly applicable to any typeof organization, and it is often used to demonstrate a supplier’s ability to control its processes.
- ISO 9000 is also an American National Standards Institute and an ASQ standard.

Three standards of ISO 9000

- ISO 9000:2000 Quality Management System—Fundamentals and Vocabulary
- ISO 9001:2000 Quality Management System—Requirements
- ISO 9004:2000 Quality Management System—Guidelines for Performance Improvement

8 clauses of ISO 9000

- (1) Scope
- (2) Normative References
- (3) Definitions
- (4) Quality Management Systems
- (5) Management Responsibility
- (6) Resource Management
- (7) Product (or Service) Realization
- (8) Measurement, Analysis, and Improvement.

Getting ISO certified

- To become certified under the ISO standard, a company must select a registrar and prepare for a certification audit by this registrar.
- There is no single independent authority that licenses, regulates, monitors, or qualifies registrars
- Preparing for the certification audit involves many activities, including (usually) an initial or phase I audit that checks the present quality management system against the standard.
  - This is usually followed by establishing teams to ensure that all components of the key clause are developed and implemented, training of personnel, developing applicable documentation, and developing and installing all new components of the quality system that may be required.
- If the company is certified, then periodic surveillance audits by the registrar continue, usually on an annual (or perhaps six-month) schedule.

Supplier quality issues

- Many organizations have required their suppliers to become certified under ISO 9000, or one of the standards that are more industry-specific. Examples of these industry-specific quality system standards are AS 9100 for the aerospace industry; ISO/TS 16949 and QS 9000 for the automotive industry; and TL 9000 for the telecommunications industry. Many components of these standards are very similar to those of ISO 9000.

Major Focus

- Much of the focus of ISO 9000 (and of the industry-specific standards) is on formal documentation of the quality system; that is, on quality assurance activities
- Organizations usually must make extensive efforts to bring their documentation into line with the requirements of the standards
- Many of the third-party registrars, auditors, and consultants that work in this area are not sufficiently educated or experienced enough in the technical tools required for quality improvement or how these tools should be deployed
- Therefore, they concentrate largely on the documentation, record keeping, and paperwork aspects of certification.
- There is also evidence that ISO certification or certification under one of the other industry-specific standards does little to prevent poor quality products from being designed, manufactured, and delivered to the customer
  - 1999–2000, there were numerous incidents of rollover accidents involving Ford Explorer vehicles equipped with Bridgestone/Firestone tires

ISO 9001:2000 Requirements

ISO 9001:2000 Requirements

4.0 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 the international standard.

4.2 Documentation Requirements

Quality management system documentation will include a quality policy and quality objectives; a quality manual; documented procedures; documents to ensure effective planning, operation, and control of processes; and records required by the international standard.

5.0 Management System

5.1 Management Commitment

a. Communication of meeting customer, statutory, and regulatory requirements

b. Establishing a quality policy

c. Establishing quality objectives

d. Conducting management reviews

e. Ensuring that resources are available

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

5.3 Management shall establish a quality policy.

5.4 Management shall ensure that quality objectives shall be established. Management shall ensure that planning occurs for the quality management system.

5.5 Management shall ensure that responsibilities and authorities are defined and communicated.

5.6 Management shall review the quality management system at regular intervals.

ISO 9001:2000 Requirements

6.0 Resource Management

6.1 The organization shall determine and provide needed resources.

6.2 Workers will be provided necessary education, training, skills, and experience.

6.3 The organization shall determine, provide, and maintain the infrastructure needed to achieve conformity to product requirements.

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

7.0 Product or Service Realization

7.1 The organization shall plan and develop processes needed for product or service realization.

7.2 The organization shall determine requirements as specified by customers.

7.3 The organization shall plan and control the design and development for its products or services.

7.4 The organization shall ensure that purchased material or product conforms to specified purchase requirements.

7.5 The organization shall plan and carry out production and service under controlled conditions.

7.6 The organization shall determine the monitoring and measurements to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of products or services to determined requirements.

8.0 Measurement, Analysis, and Improvement

8.1 The organization shall plan and implement the monitoring, measurement, analysis, and improvement process for continual improvement and conformity to requirements.

8.2 The organization shall monitor information relating to customer perceptions.

8.3 The organization shall ensure that product that does not conform to requirements is identified and controlled to prevent its unintended use or delivery.

8.4 The organization shall determine, collect, and analyze data to demonstrate the suitability and effectiveness of the quality management system, including

a. Customer satisfaction

b. Conformance data

c. Trend data

d. Supplier data

8.5 The organization shall continually improve the effectiveness of the quality management system.

A WORD OF CAUTION

- It has been estimated that ISO certification activities are approximately a $40 billion annual business, worldwide.
  - Much of this money flows to the registrars, auditors, and consultants.
  - This amount does not include all of the internal costs incurred by organizations to achieve registration, such as the thousands of hours of engineering and management effort, travel, internal training, and internal auditing.
- It is not clear whether any significant fraction of this expenditure has made its way to the bottom line of the registered organizations.
- Furthermore, there is no assurance that certification has any real impact on quality

The Malcolm Baldrige National Quality Award

- The Malcolm Baldrige National Quality Award (MBNQA) was created by the U.S. Congress in 1987
- It is given annually to recognize U.S. organizations for performance excellence.
- Awards are given to organizations in five categories: manufacturing, service, small business, health care, and education.
- The award is administered by NIST (the National Bureau of Standards and Technology).
- The criteria are directed towards results, where results are a composite of customer satisfaction and retention, market share and new market development, product/service quality, productivity and operational effectiveness, human resources development, supplier performance, and public/corporate citizenship

Performance Criteria



FIGURE 1.10 The structure of the MBNQA performance excellence criteria. (Source: Foundation for the Malcolm Baldrige National Quality Award, 2002 Criteria for Performance Excellence.)

Performance Excellence Categories and Point Values

1	**Leadership**		**120**
	1.1 Leadership System	80	
	1.2 Company Responsibility and Citizenship	40	
2	**Strategic Planning**		**85**
	2.1 Strategy Development Process	40	
	2.2 Company Strategy	45	
3	**Customer and Market Focus**		**85**
	3.1 Customer and Market Knowledge	40	
	3.2 Customer Satisfaction and Relationship Enhancement	45	
4	**Information and Analysis**		**90**
	4.1 Measurement and Analysis of Performance	50	
	4.2 Information Management	40	
5	**Human Resource Focus**		**85**
	5.1 Work Systems	35	
	5.2 Employee Education, Training, and Development	25	
	5.3 Employee Well-Being and Satisfaction	25	
6	**Process Management**		**85**
	6.1 Management of Product and Service Processes	45	
	6.2 Management of Business Processes	25	
	6.3 Management of Support Processes	15	
7	**Business Results**		**450**
	7.1 Customer Results	125	
	7.2 Financial and Market Results	125	
	7.3 Human Resource Results	80	
	7.4 Organizational Results	120	
	Total Points		**1,000**

MBNQA Process

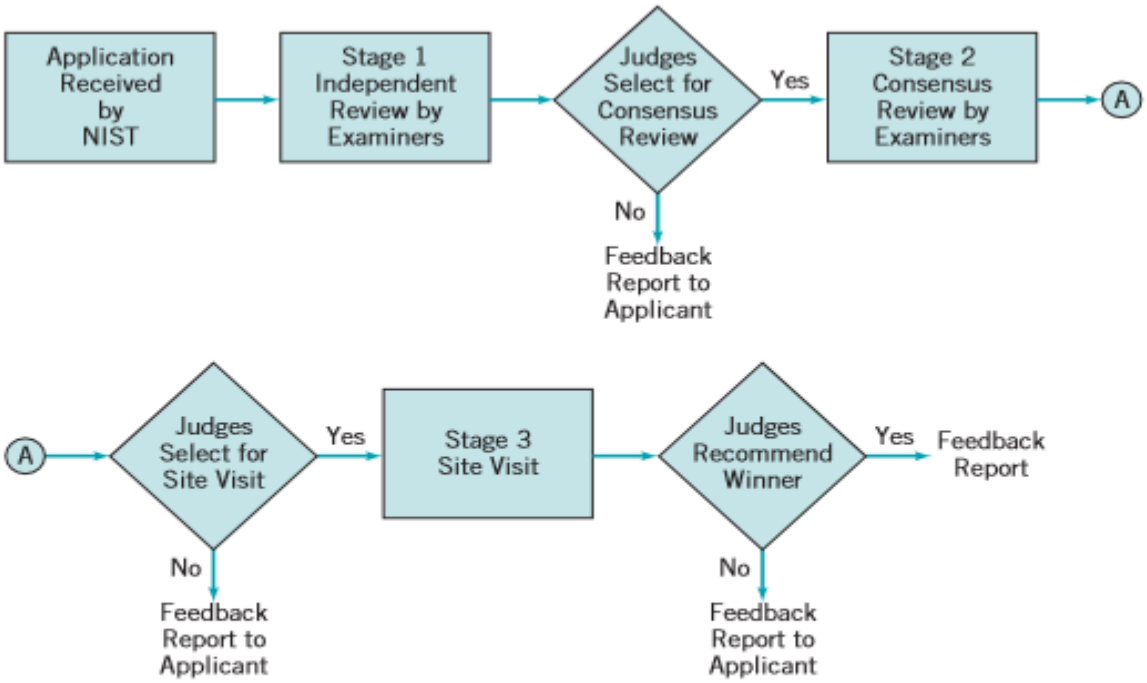


FIGURE 1.11 MBNQA process.
(Source: Foundation for the Malcolm Baldrige National Quality Award, 2002 Criteria for Performance Excellence.)

Further References

- http://www.iso.org/iso/iso_9000
- http://asq.org/learn-about-quality/iso-9000/overview/overview.html
- https://en.wikipedia.org/wiki/ISO_9000