1. Introduction to ISO 9000 : 2000

ISO 9000, the world's leading standards series for Quality Management Systems, has been revised, following extensive user consultation and overwhelming endorsement by ISO member bodies. The new series of revised standards, embracing ISO 9000, ISO 9001, ISO 9004 and ISO 19011 has been completely revitalized with the emphasis very much on making the standards more streamlined and user friendly for business. The new standards mark a significant and welcome shift from procedure to process based activities, reflecting more accurately the way in which organizations actually work. The revised standards will be particularly attractive to the services sector, since the manufacturing bias of the earlier editions has been effectively eradicated.

Whether you are an established ISO 9000 user or are thinking of introducing a formal Quality Management System (QMS) to your organization for the first time, ISO 9000:2000 holds the key to greater business effectiveness.

As some 500,000 organizations across the world set about implementing the important enhancements contained in the new standards, NSAI can offer a full range of services to support ISO 9000:2000.

In the following sections you will find essential introductory information outlining the objectives and primary features of the new standards. In addition:

- NSAI Standards Sales have hard copies of the revised standards for sale and for the first time a CD-ROM version is also included.

- NSAI Certification Services are fully accredited to handle the new revisions and are working with companies making the transition to the new standards or implementing ISO 9000 for the first time.

- NSAI Training Services offer a complete suite of courses to bring your staff up to date on the implications of the new standards.

- NSAI Standards Information Service have organized occasional free half day technical meeting on the ISO 9000:2000 series.

2. The ISO 9000:2000 Series

The ISO 9000:2000 series consists of four separate, but closely related standards:

ISO 9000:2000 Quality Management – Fundamentals and Vocabulary

This describes the fundamentals of quality management systems, and specifies the terminology for quality management systems used throughout the series. An Annex to the standard illustrates concept relationships relating to quality, management, documentation, audit etc.

ISO 9001:2000 Quality Management Systems – Requirements

This specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that meet customer requirements. The ISO 9001:2000 specification provides the basis for quality systems certification or registration.

All users of ISO 9001:1994, ISO 9002:1994 or ISO 9003:1994 will now need to migrate to the single requirements standard, ISO 9001:2000, during the NSAI transition period. For the future it is the only standard in the series to which organizations can be certified or registered.

ISO 9004:2000 Quality Management Systems – Guidelines for Performance Improvements

ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The aim of this standard is improvement of the performance of the organization and satisfaction of customers and other interested parties. ISO 9001:2000 and ISO 9004:2000 have been produced as a consistent pair of standards and should be used in close harmony.

ISO 19011:2002 Guidelines on Quality and/or Environmental Management Systems Auditing

ISO 19011 provides guidance on the management of audit programmes, the conduct of internal or external audits of quality and/or environmental management systems, as well as on the competence and evaluation of auditors.

ISO 9000:2000, ISO 9001:2000, 9004:2000 and ISO 19011:2002 are intended to form a coherent set of quality management system standards facilitating mutual understanding in national and international trade.

3. Background to the ISO 9000:2000 Revisions

ISO Standards are reviewed periodically to decide whether they need confirmation, revision or withdrawal. This is to ensure that they take account of technological and market developments and that they remain the state of the art. The ISO 9000 series was first published in 1987 and it was not until 1994 that the first revisions were published. The reason was that management systems were new to many of the organizations engaged in establishing quality systems on the basis of the ISO 9000 standards. In this situation, ISO/TC 176, the committee responsible for the standards, felt that making major changes in the standards could run the risk of disrupting such efforts. Consequently, the 1994 revisions were relatively minor and mostly concerned with removing internal inconsistencies.

However, the Year 2000 revisions represent a thorough overhaul of the standards to take into account developments in the field of quality and the considerable body of experience that now exists in implementing ISO 9000.

The Year 2000 revisions have been subjected to what must be the most intense scrutiny ever of any of the 12,700 International Standards developed by ISO since it began operations in 1947.

The extraordinary care taken in the development of ISO 9000:2000 is a measure of the international impact that the ISO 9000 standards have had since their first publication in 1987. A recent edition of '*The ISO Survey'* reveals that at the end of 2001, the number of ISO 9000 certificates issued worldwide totalled 510,616 in 161 countries. This was an increase over the previous year of 101,985.

Fully conscious of its responsibility, ISO TC 176 has broken new ground in terms of its approach to the revisions and the entire programme has been carried out in conjunction with a series of supporting measures and services in which Ireland has fully participated.

These measures have included a survey to help define user requirements for the year 2000 revisions; verification of the drafts against the design specifications for the standards; validation to determine if they will meet user needs, and encouragement of users to submit comments on the evolving drafts in order to improve the documents further. Added to these measures aimed at product enhancement are information services, such as the positing of regular updates on the ISO web site (www.iso.ch). These measures have kept ISO 9000 users in the information loop as the revisions progressed and encouraged broadbased comment on the evolving documents at each development stage in order to improve them still further.

Many users in Ireland have taken the opportunity to monitor the evolution of the draft standards as they progressed through the CD1 (July 1998), CD2 (February 1999), DIS (November 1999) and FDIS (September 2000) stages leading to publication on 15 December 2000. ISO 19011 was published in October 2002.

Throughout the revision programme, the NSAI Quality Management Standards Committee (QMSC) has kept users informed of developments nationally, while the TC176/SC2 web site has provided official status reports, frequently asked questions and draft guidance documents.

4 Quality Management Principles

In order to lead and manage an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing an organization encompasses quality management amongst other management disciplines.

Eight quality management principles underline the ISO 9000:2000 standards and have been identified as a framework towards improved performance of an organization. They are aimed at helping organizations to achieve sustained success.

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.

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.

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.

4.   Process approach

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

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.

6.   Continual improvement

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

7.   Factual approach to decision making

Effective decisions are based on the analysis of data and information.

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.

These eight quality management principles are fundamental to the development of any quality management system meeting the ISO 9000:2000 series requirements.

5. ISO 9000:2000 The Main Changes

There are many changes in ISO 9000:2000 and it is imperative that the user studies the implications of the changes in relation to their own organization. The following are some of the highlights of the new standards:

- The number of standards in the ISO 9000 family has been reduced, simplifying selection and use. The "core series" is now made up of four standards designed to be used as an integrated package for maximum benefit.

    - ISO 9000, Quality Management Systems – Fundamentals and Vocabulary;
    - ISO 9001, Quality Management Systems – Requirements (henceforth, the sole certification or registration stand in the series);
    - ISO 9004, Quality Management Systems – Guidelines for Performance Improvements
    - ISO 19011, Guidelines on Quality and/or Environmental Management Systems Auditing.

- The undue emphasis on ISO 9000 certification, as opposed to using the standards for quality improvement, has now been corrected. ISO 9001:2000 and ISO 9004:2000 have been expressly designed for use in combination as a "consistent pair".

- Although large manufacturing organizations were the first to adopt the ISO 9000 standards, new implementations in many countries are increasingly by small and medium enterprises, by the service sector and by public administrations. To simplify understanding and to ease implementation in these sectors, the language of the revised standards is less manufacturing industry-oriented, and more user-friendly.

- The question as to how to choose between ISO 9000 implementation, the pursuit of national quality award, or embarking on a Total Quality Management (TQM) programme has been addressed. In fact, there has never been any need to choose one of these options and exclude the others. The ISO publication *'ISO 9000 + ISO 14000 News'* has several times surveyed major quality award winners and found that most operated an ISO 9000 quality system, which was the foundation for other quality initiatives, such as pursuing a national or regional quality award or TQM. The revised ISO 9000 standards make such combinations easier. The standards are based on eight quality management principles. ISO 9004 also includes a self-assessment questionnaire to assist organizations in determining and raising their level of quality "maturity" – which could be of use whether in relation to their ISO 9000 quality system, in pursuit of an award, or a TQM programme.

- While most organizations are still managed by means of functional, hierarchical structures, products and services are produced, sold and delivered by business processes which operate cross-functionally. These processes take inputs from a number of sources, and blend, or transform them (add value) to produce desired outputs. The ISO 9000:2000 standards are restructured on a business process model which more accurately represents the way organizations actually operate rather than the linear 20-clause structure of the ISO 9001:1994 standard. The foundation of the structure are the four new main clauses comprising : Management Responsibility, Resource Management, Product Realization and Measurement, Analysis and Improvement.

- "Quality" in the ISO 9000 series means meeting customer requirements. This focus is reinforced in the revised standards by the addition of a requirement for monitoring customer satisfaction.
- The responsibilities of top management in relation to quality are reinforced and extended in the revised standards, including requirements for communication with staff and customers.

- The ISO 9000:2000 series explicitly makes continual improvement a requirement and the Plan-Do-Check-Act cycle is an integral part of the revised standards.

- ISO 9001:2000 has been designed for maximum compatibility with ISO 14001, the environmental management system standard, and the recently published auditing standard, ISO 19011, is applicable to both quality and environmental auditing.

To assist users of the new ISO 9000:2000 standards, ISO/TC176/SC2 has published a number of guidance modules, which may be freely downloaded from the NSAI website.   Feedback from users of the standards will be used to determine whether additional modules should be developed, or if the published modules should be revised.

The following modules are currently available :

- Guidance on ISO 9001:2000 clause 1.2 'Application'.
- Guidance on the Documentation requirements of ISO 9001:2000.
- Guidance on the process Approach to quality management systems.
- Guidance on the Terminology used in ISO 9001:2000 and ISO 9004:2000.

6.   Process Approach

One of the most striking changes in the ISO 9000:2000 revision is the move away from a procedures based approach to management to a process based approach to management.

Any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process.

For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes is referred to as the "process approach".

The figure below illustrates the process-based quality management system described in the ISO 9000:2000 series of standards. The illustration shows that interested parties play a significant role in providing inputs to the organization. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to the extent to which their needs and expectations have been met.

Figure 1 — Model of a process-based quality management system
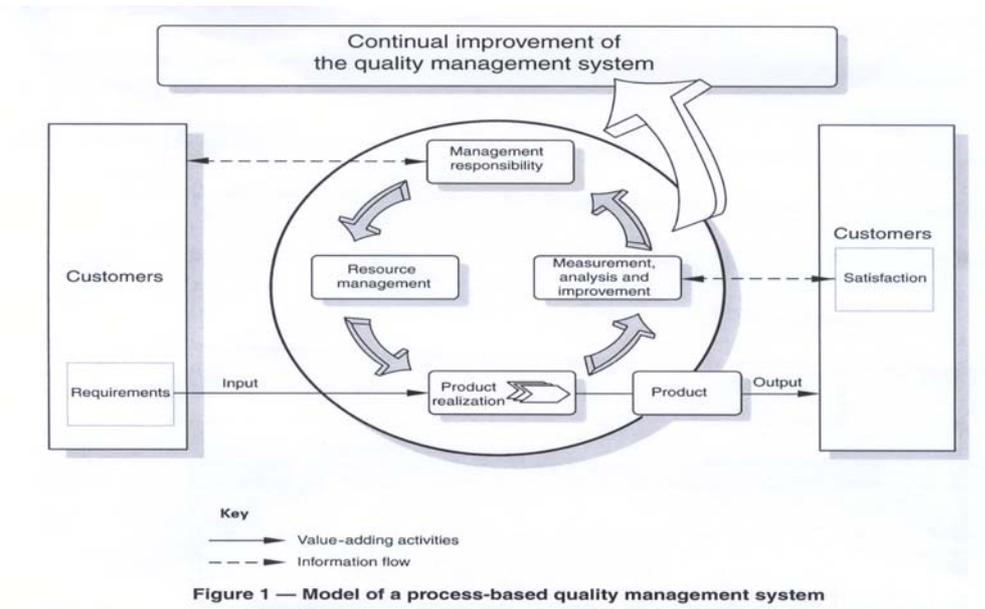
7. Clause 1.2 "Application"

One objective of the Year 2000 revision to the ISO 9000 family of standards was to simplify the structure and reduce the number of standards within the family. This has been achieved by the replacement of ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994 by a single quality management system requirements standard, ISO 9001:2000.

ISO 9001:2000 is intended to be generic, and applicable to all organizations, regardless of type, size and product category. It is recognised, however, that not all the requirements of this new standard will necessarily be relevant to all organizations. Under certain circumstances, an organization may be able to justify the exclusion of some specific ISO 9001:2000 requirements from its quality management system. ISO 9001:2000 requirements makes allowances for such organizations, through clause 1.2 ("Application").

Clause 1.2 states the following :

"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 organisation's ability, or responsibility, to provide product that fulfils customer and applicable regulatory requirements".

The consolidation of ISO 9000, ISO 9002 and ISO 9003, together with the advent of clause 1.2, has lead to some user questions in relation to topics such as design and development. In order to help ISO 9000 users, particularly those who have been using ISO 9002:1994 for certification purposes, a guidance document has been developed to provide information regarding the intent of clause 1.2 of ISO 9001:2000 including some typical examples of its use in practical situations.

8. ISO 9000:2000 and Top Management

ISO 9000:2000 speaks the language of business more clearly than ever before and addresses the issue of management responsibility in unequivocal terms. Indeed, one of the four new main clauses of ISO 9001:2000 is now concerned with Management Responsibility.

The term "top management" is mentioned on no fewer than nine occasions in Clause 5 (Management Responsibility) and lest there be any ambiguity as to who top management is, the following definition is given in ISO 9000:2000, "person or group of people who direct and control an organization at the highest level".

All of this means that the role of top management in areas such as organizational direction, purpose, policies, objectives, review and culture must be regarded as central to the success of ISO 9000:2000.

ISO 9000:2000 now mandates as a requirement, that top management provide objective evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness.

9. Principal Benefits of ISO 9000:2000

ISO 9000:20000 builds upon the 15 year track record of ISO 9000 and makes a good product even better. Some of the principal benefits of the new standards series include :

- The ISO 9000:2000 series is restructured on a business process model, which more closely corresponds to the way organizations actually operate and should result in quality management systems that are more effective, easier to implement and audit.

- The language of the ISO 9000:2000 version has been crafted to make the standards easier to understand and implement by organizations large and small, manufacturing or service, in public or private sectors.

- The reinforced requirement for customer satisfaction and the inclusion of requirements for monitoring customer satisfaction and for continual improvement will ensure that user organizations not only "do things well" (efficiency), but also "do the right things" (effectiveness).

- The ISO 9000:2000 series goes beyond meeting customer requirements to enhancing customer satisfaction. The revised standards can be used as a stepping-stone for achieving Total Quality Management (TQM). They are based on eight Quality Management Principles, which are clearly spelled out in ISO 9000 and ISO 9004. These principles cover the basic concepts of many quality awards.

- The design and development of ISO 9001:2000 and ISO 9004:2000 as a strongly linked "consistent pair" providing organizations with a structured approach to progress beyond certification to the achievement of Total Quality Management (e.g. satisfaction not just of customers, but of all interested parties – shareholders, employees, suppliers, the local community, society as a whole).

- ISO 9001:2000 has been designed to have maximum compatibility with ISO 14001, the environmental management system standard. ISO 19011, allows for joint and/or combined audits of quality and environmental management systems.

- ISO 9000:2002 has reduced the requirements for documented procedures. Draft guidance on documentation requirements of ISO 9001:2000 has been drawn up to help users in this regard.

10. Purchasing ISO 9000:2000

I.S. EN ISO 9000:2000, the national implementation of the ISO 9000:2000 series, may be purchased from NSAI Standards Sales at the following address (mail only, no personal callers)

ILI
Northumberland House
42/44 Northumberland Road
Dublin 4

Tel: +353 1 857 6730 or 857 6731
Fax: +353 1 857 6729
E-mail: info@standards.ie

The I.S. EN ISO 9000:2000 publication consists of ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000 together with a CD-ROM containing all three standards.

I.S. EN ISO 9001:2000 is also available singly in hard copy format only.