The new ISO 9001:2000 Standard

Background

The ISO[1] 9000 standards are a set of international Quality Management standards and guidelines, which were first published in 1987, since then they have earned a global reputation as the basis for establishing Quality Management Systems (QMS)[2] in all types and size of organisation.

Three of the current standards, ISO 9001, 9002 and 9003, have been used extensively as the basis for independent or third party quality system certification. This has resulted in over two hundred thousand organisations world-wide being officially certified. There are many more in the process of setting up and implementing Quality Management Systems.

The standards go through a review cycle every five years to decide if they are still effective, need to be updated or are no longer required and should be withdrawn. This process has just been completed and a new updated version of the standard was formally launched on the 15th December 2000 (ISO 9001:2000).

Change of structure

The review process decided that the current ISO 9000 group of standards, which comprises over twenty standards, should be simplified and therefore they have been reduced to three Quality Management System standards:

- ISO 9000: 2000 - QMS – Fundamentals and vocabulary
- ISO 9001: 2000 - QMS – Requirements
- ISO 9004: 2000 - QMS – Guidelines for performance improvement

In addition, there will be a small number of standards and/or technical reports to address specific issues.

There will be one QMS requirements standard, ISO 9001, which will replace the current ISO 9001, ISO 9002 and ISO 9003.

ISO 9004 will be the 'QMS Guidance For Performance Improvement' standard and will form a consistent pair with ISO 9001, with the same sequence and numbering. They are applicable to small, medium and large organisations in the public and private sectors, and will equally apply to users in industrial, service, software and other areas.

Copies of the new version of the Standard are now available through the NSAI Standards Office.

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[1] *ISO – International Standards Organisation*

[2] *QMS Definition – Management System to direct and control an organisation with regard to quality ISO 9000:2000 Fundamentals and Vocabulary)*

Introduction of a process model approach

The new ISO 9001:2000 standard has been developed based on a process model using eight quality management principles. The model advocates that organisations should move towards business excellence and places a much greater emphasis on achieving customer satisfaction.

ISO 9004:2000 uses the same process model and quality management principles, but has an emphasis on satisfying the needs of all interested parties.

The revision reflects the evolving 'Quality Management' practice but retains the essential elements of the previous (1994) edition.

Who will the changes affect?

The new version of the standard will affect those members with existing ISO 9001 Certification (including TickIT) and also those considering implementing Quality Systems in the near future.

This includes the following group of standards:

ISO 9001:1994 Quality Systems
  – Model for Quality Assurance in design/ development, production, installation and servicing.

ISO 9002:1994 Quality Systems
  – Model for Quality Assurance in production, installation and servicing.

ISO 9003:1994 Quality Systems
  – Model for Quality Assurance in final inspection and test.

Major changes that have been implemented

- The ISO 9001:2000 title has been changed to remove the reference to "Quality Assurance". This reflects the need for an organisation to not only address Quality Assurance of their product and/or service, but also includes the need to demonstrate its capability to achieve customer satisfaction. The new title will be "ISO 9001: 2000 Quality Management Systems -Requirements."

- The 1994 version of the ISO 9001 standard was not easy to interpret for software organisations and a Guideline document ISO 9000-3 was written to provide guidance for the application of ISO 9001 to the development, supply and maintenance of software. When the new version of the standard is introduced ISO 9000-3 will become obsolete. The new standard is simpler, and by using the process model approach is much nearer to the generic Life Cycle models used and understood by software organisations. This makes the new standard much easier to follow for all types of software organisation.

- The original structure of the 1994 version of ISO 9001 is being simplified, there will no longer be twenty key subjects instead there will be four main headings covering:

    - Management Responsibility
    - Resource Management
    - Product realisation (Management of the key processes)
    - Measurement, Analysis and Improvement

    In addition the new standard gives much more emphasis to continuous improvement, resource planning & management.

- The new standard concentrates more on ensuring that you have adequate records for key areas, taking the emphasis away from too many procedures, one of the criticisms of earlier versions of the Standard. There are only 6 core procedures required by the new version of the standard.

- The Standard is being developed as a part of a pair of standards, the other part being *ISO 9004: 2000 Quality management systems – Guidance for performance improvement*.

What do these changes mean to you?

Organisations already certified to ISO 9001 or ISO 9002 (including TickIT)

If your organisation already has ISO 9001 or ISO 9002 certification you will need to update your Quality Manual and procedures etc., to reflect the structure and requirements of the new ISO 9001:2000 standard. There is also a need for you to address the increased emphasis on Continuous Improvement, Resource Planning and Management.

There will be a transition period of 3 years for those companies with existing certification you will be expected to have made the necessary changes no later than December 2003.

How can CSE help Software Companies with upgrade?

CSE runs a *1-day training event* on *"How to update your Quality System to meet the new ISO 9001:2000 requirements"* specifically for Software Companies. The course not only explains the changes that are being implemented and why, but will ensure that you are fully briefed on what changes your organisation must make in order to retain ISO certification to the new standard.

CSE also offers a one-to-one consultancy service for organisations wanting individual assistance with upgrading existing quality systems.

Organisations currently implementing or thinking of implementing Quality Systems to ISO 9001

You must make sure that what you are building will satisfy the requirements of the new version of the standard.

How can CSE help?

CSE runs a *2-day training event* called the *"Introduction to Quality Systems and the ISO 9001: 2000 Standard".* This event is for Software Companies that do not have existing Quality Systems but who would like to know more about Quality Systems and the new ISO 9001:2000 standard and it's relevance to their business. The course will enable you to make an informed decision about whether to go for ISO 9001 certification or to simply implement a Quality System without the formal approval of ISO. This course is run on an in-house basis for an individual company.

Cluster Approach

CSE also runs a 12-month programme helping small software companies to implement a quality system in a structured way. Using the cluster approach where a group of companies' progress together has proved to be a cost-effective option for the smaller software organisation.

Information on all the above courses can be found on CSE's web site http://www.cse.dcu.ie or contact CSE Admin on 01-700 5750.

Further Information:

To discuss in more detail call Jill Pritchet at CSE on 700 8055 or Email jill@cse.dcu.ie for assistance.

Useful Reference Web sites:

National Standards Authority of Ireland (NSAI): http://www.nsai.ie
Tickit Office: http://www.tickit.org
International Organisation for Standardisation (ISO): http://www.iso.ch