Chapter 1

Introduction

In 1983 the thrust of the message in the UK Government's White Paper on Standards, Quality and International Competitiveness was that British Industry should utilize national standards and quality assurance as a means to improve its competitiveness. The quality system standards used to spearhead this campaign were born out of the defence industry where there was a long tradition of command and control. As a consequence, ISO 9001 followed the same pattern of imposing requirements to prevent failures that experience had shown led to poor product quality. This approach adopted in the early 1980s by a few thousand organizations, dominated by the manufacturing sector, mainly in the UK has now grown to a million organizations worldwide, covering the whole spectrum of sectors from government, hospital, education, manufacturing to service industries.

During this time there has been a growing recognition that quality does not result from simply imposing rules, but from the need for organizations to create and maintain an environment in which people are motivated to do the right things right without having to be told. The ISO 9000 family of standards reflected that recognition. The bureaucracy has been replaced by 8 Quality management principles that *aim to help organizations to achieve sustained success*[3].

For the designers and managers of the organization's quality management system these principles are the key to a successful implementation of ISO 9001.

For the auditors they are the key to transforming the way quality system audits are conducted, as recognised by the International Accreditation Forum (IAF).

In response to ISO 9001:1994 most organizations created documentation that focused only on those requirements which were addressed by the Standard. It was believed that by documenting what you do and doing what you document against each specific requirement in the Standard, product quality would improve.[4] As some of the principal factors affecting the quality of output such as behavioural factors were missing, conformity with ISO 9001:1994 did not stop organizations avoiding quality problems.

This narrow view of quality management was swept aside by ISO 9000:2000 (now ISO 9000:2005) and in its place it encourages *organizations to*[5]*:*

a) *determine the needs and expectations of customers and other interested parties;*

b) *establish the quality policy and quality objectives of the organization;*

c) *determine the processes and responsibilities necessary to attain the quality objectives;*

d) *determine and provide the resources necessary to attain the quality objectives;*

e) *establish methods to measure the effectiveness and efficiency of each process;*

f) *apply these measures to determine the effectiveness and efficiency of each process;*

g) *determine means of preventing nonconformities and eliminating their causes;*

h) *establish and apply a process for continual improvement of the quality management system.*

This simple, yet powerful message is there for all to see and understand. However, one might be forgiven (but only momentarily) for missing it if on reading the Standard one only looks for and sees many of the old familiar phrases. We are creatures of habit and tend to resist change.

It does appear that the committees involved in drafting ISO 9001:2000 unnecessarily retained many of the old requirements in the new version. It was clear that an opportunity was missed to create a far simpler, shorter Standard, even reducing it to a page or two, which would have enabled everyone to see a clear line of sight from the Standard to customer satisfaction. It would have been a far more effective tool for system design and auditing for it is the detail requirements that cause auditors to loose sight of the objectives.

Since the introduction of the ISO 9000 family of standards the certification bodies have pursued an approach of raising nonconformities because either the words in the Standard have not been met or the organization has not done what it said it would do. There has been no examination of output results, but it is the improvement of these results that improves the competitiveness of

industry not conformity with procedures. Organizations continue with the conformity approach to auditing because Certification Bodies do the same. Organizations must change the focus of their quality management system and auditors must change their approach.

The 2008 revision of ISO 9001 was not a major one, seeking primarily to

"introduce clarifications to the existing requirements of ISO 9001:2000 and to improve compatibility with ISO 14001:2004"[6]

With respect to external auditing, the IAF requires auditors to demonstrate knowledge of the Quality management principles and the concepts and terminology of the Standards. With respect to internal auditing, and to achieve sustained success, organisations require auditors to play their part in improving performance. This requires a change in questioning technique.

No longer should auditors open their questioning with:

*"Have you got a procedure for *******? – Show me"*

It is more likely to be:

*"What improvement in results was obtained from your last review of the ******** process? – Show me"*

We call this technique the *process approach to auditing*.

It is simple but powerful!