



Perspectives of ISO/TC 176 leaders

2007 is the 20th anniversary of ISO 9001, the International Standard for quality management that is certainly the best known of ISO's more than 16 500 standards. This Special Report provides different perspectives on the impact of ISO 9001. In this opening article, the Chairs of ISO/TC 176, Quality management and quality assurance, and its subcommittee SC 2, Quality systems, share their perspectives on the standard that took quality management from the production lines to the boardroom and from manufacturing to services and public administration.

ISO 9000 – We've come a long way...



by **Trevor Smith**,
Chair of ISO/TC 176 since 2002

One can hardly enter a city, drive a major highway or surf the Internet without seeing “ISO 9001 registered” on bill boards, on company vehicles, buildings and Web sites. Indeed, the ISO 9001 “brand” has today become associated with a variety of businesses visible in everyday life.

But what many people are not aware of is how the standard has transformed business partnerships along the supply chain, served specific sectors and is used by organizations of all sizes as a solid platform, framework or model on which to build a system that ensures customer requirements are met and that continual improvement is built into the organization's culture.

Standards often conjure up thoughts of maintaining status quo and are seen as irrelevant to dynamic business growth. Applied properly, however, management system standards have been shown to set the framework for growth and international communication (a common “language”) and to serve as platforms for excellence.

**The inauguration of
ISO 9000 20 years ago
charted the beginning of
a new era**

Preceded by materials and product standards, ISO 9000 was the first international management system standard, and

its inauguration 20 years ago charted the beginning of a new era.

It is appropriate that the ISO technical committee ISO/TC 176, which manages the development and review of the ISO 9000 standards, is ISO's largest committee with 98 member countries (participants or observers) and 39 liaison organizations (ranging from other standards-developing committees to business associations and international or regional organizations).

ISO 9001:2000 is the standard that sets out requirements for a quality management system. It is the principal standard in the ISO 9000 family that is used for certification (ISO 10012, for

measurement assurance, may also be used for certification). There are 15 other standards in the family which provide guidance on specific topics such as performance improvement, auditing and training. In addition, there is other material freely available on the ISO Website (www.iso.org).

It should be emphasized that beyond the more than 800 000 ISO 9001 certifications worldwide today, there are many organizations and sectors (manufacturing, services, governments, healthcare facilities, etc.) that use ISO 9001 and related guides to improve their internal, supplier and customer-facing processes to meet the ever-changing challenges of customers today.

As Chair of ISO/TC 176 since 2002, it has been my pleasure to observe the work of the committee as it evolves its own business processes to mature, grow and adapt to meet user needs.

Cutting edge

On account of the generic nature of many of our standards (our “products”), liaison with other bodies of standards developers and stakeholder groups has been essential. With the help of our TC and subcommittee leadership, we have strived to keep on the cutting edge of user and societal needs.

In the last few years, greater interest has emerged in the utility of a systems approach as the “engine” or “DNA” of management and new are-



as such as food safety, supply chain and information security, for which new management system standards have been developed.

The ISO Technical Management Board (TMB) has asked that the existing management system resources within ISO/TC 176 (quality) and ISO/TC 207 (environment) help with new developments to ensure alignment between standards, simplicity and market relevance. We are seeing excellent partnerships grow so that standards in general and ISO standards in particular meet market requirements.

The next 20 years will, I am sure, spawn new changes. Is ISO up to the challenge of continuing to provide products that promote international trade, supply chain partnerships and societal well being? I believe it is able to do so.

More than anything, ISO is people, many of whom are volunteers, representing their country or their organizational sector. I am very thankful for the people in ISO/TC 176 who, together with ISO Central Secretariat staff in Geneva and national standards bodies, have helped ISO 9000 make a contribution in the past 20 years. Our goal is that we continue to produce standards that add value for many more years to come. ●

The ISO 9000 phenomenon



by **John Davies**,
Chair of ISO/TC 176/SC 2
since 1987

We are now looking at **how** an organization can achieve sustained success

It is 20 years since the first editions of the ISO 9000 standards were published – and what a journey it has been!

Originating in the military, nuclear and construction fields as quality assurance standards, they grew through civilian use into national standards before being submitted in 1979 to ISO for development into International Standards.

The ISO 9000 standards began as a limited series of six standards, and expanded until at one time there were 21 standards in the family. The ISO 9000 family has since been reduced to a more focused set of 16 standards.

The ISO 9000 family consists of the well-known ISO 9001:2000 quality management systems requirement standard, along with a vocabulary and numerous guidance standards. In addition, the ISO 9000 family is supported by the handbook, *ISO 9000 for Small Business*, *ISO Management Systems* magazine, as well as free information on ISO's Web site, including online brochures and guidance notes.

The core standards are now in their 3rd editions (1987, 1994, and most recently the 2000 editions), and are now being revised to maintain their currency and relevance for the future.

Originally focussing on “quality assurance”, they have matured to cover a much wider spectrum of “quality management”, to assist organizations in achieving greater customer satisfaction, as well as that of other stakeholders.

They have also progressed from containing discrete requirements to encompassing a full process approach that embodies the Shewhart/Deming “Plan-Do-Check-Act” cycle.

Unprecedented usage

Why is ISO 9000 referred to as a phenomenon? It is because their unprecedented usage, as recorded annually by *The ISO Survey*. The first edition of this survey in January 1993 recorded nearly 28 000 certificates of conformity in 48 countries. At the end of 2005, the total was nearly 777 000 in 161 countries.

What is even more amazing is that the founding members of

the ISO technical committee responsible for these standards, ISO/TC 176, had no expectation that ISO 9001 would be such a success. It was initially thought that this most widely used of all ISO standards would have a limited effect on the market. Their initial expectation was that the more substantial ISO 9004 guidance standard would predominate.

One of the key strategic changes that has occurred over the years is the approach taken to sector-based quality management schemes. Historically, ISO 9001 sought to eliminate the need for sector variants, whereas today, we consider ISO 9001 to be the generic “engine” that sectors customize to meet their specific needs.



The Lawrence D. Eicher Award for excellence in creative and innovative standards' development was presented to ISO/TC 176/SC 2 in 2004 and ISO Secretary-General Alan Bryden (right) took advantage of a visit to Ireland during the subcommittee's June 2006 meeting in Tralee to re-present it to SC 2 Chair, John Davies, in the presence of nearly 100 SC 2 members.

This new sector approach has been very successful, and has led to the establishment of major quality programmes in a number of sectors, such as those for the automotive, aerospace, petroleum/petrochemical and natural gas, and telecommunications industries, to name but a few. This approach has also enabled the standard to be used as the basis for regulations or regulatory standards, such as for medical devices.

More recently, ISO has started publishing standards in other management systems fields, such as those for food safety, information technology security, and especially the ISO 14001 standards for environmental management. A great deal of effort has been expended in coordination with the developers of those standards to achieve compatibility between them and ISO 9001, to ensure that an organization that wishes to use them in conjunction with ISO 9001 can easily do so.

One of our critical activities for the future is to further improve the alignment of ISO 9001 with the standards from other fields, to make it easier for organizations to use them in an integrated manner to meet their business needs.

The ISO Survey
of Certifications
2006

Sustained success

Through our current revision of ISO 9004, of which the current edition provides guidelines for achieving performance improvements, we are now looking at how an organization can use the philosophy of quality management to achieve sustained success, to the benefit of its stakeholders and customers.

The ISO 9004 standard is also planned to include an assessment tool to enable organizations to determine their relative maturity on the path towards sustained success, and to help identify improvement actions that may be needed.

For many products, reaching their 20th birthday would be a cause for concern. For the ISO 9000 family of standards, with its constant striving to give value to its users through regular updating and renewal, this is a cause for celebration, and is reflected by the increases year after year in the numbers of organizations that look to ISO 9000 to meet their business needs.

None of this would have been possible without the hard work and dedication of the experts who sit on ISO/TC 176, their supporting organizations and national standards bodies, and the fantastic feedback and support that we have received, and continue to receive, from users of the standards. We can only give these expert volunteers our grateful thanks for the past, and our hope that they will be with us for the future. •

Reliable foundation for global trade



by **Reginald N. Shaughnessy**,
Chair of ISO/TC 176 from 1984
to 1998

The problems caused by multiple audits against proprietary specifications are now in the distant past

Third party certification of organizations meeting the requirements of ISO 9000 standards (since 2000, ISO 9001 is the only certification standard) provides hard statistics on the growth in their use, but one may ponder at the rate and extent.

Obviously, in determining the overall impact of ISO 9000, there are no reliable statistics regarding the internal use of the standards for self-management or procurement reliability. However, literature abounds with commentaries of the beneficial impact experienced in these applications.

At the genesis of ISO/TC 176 in 1979, international trading patterns were at the cusp of change with the earlier formation of The World Trade Organization (WTO) and its goals of reducing trade tariff and non-tariff barriers to achieve future success in globalization.

The notions of standardization in the area of “soft” management standards and of generic quality system standards were the subject of much debate, the only previous experience being with procurement standards for critical applications such as military supplies and the nuclear industry where the issue of dependability was obviously critical.

Proprietary systems

At that time, tools and practices for efficient and reliable production were more associated with proprietary systems or application of fundamental principles as embodied by Drs. Deming and Juran with

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statistical process control, principles of management, Dr. Phil Crosby's cost of quality, Japanese production methods, European quality assurance – to name but a few.

In this context, the first major impact was the unquestionable demonstration in the 1987 version of the standard that a generic system for quality which would be compatible with the management structure of an organization was not only feasible, but beneficially implementable on an international basis.

The effect of this initial success was that whilst organizations had options in pursuing proprietary systems of their own choosing, there was a foundation available for “levelling the playing field” for international trade and future global trading networks.

The notion of conformity assessment and the development of third party certification to a standardized curriculum, compatible with a company's own management system, became a major opportunity with the publication of the ISO 9000 series, enhanced later with the more mature 1994 editions.

During the period 1987-1996, the ISO 9000 series provided a major, reliable system for developing countries, helping them with effective tools and verifiable evidence of their competence levels to participate responsibly and with confidence in the emerging global trade arena.

Multiple audits

For companies in the developed countries, the problem of the cost and aggravation of multiple verification audits to demonstrate reliability and predictability in order to minimize waste and risk had become a serious cost drain. Prior to 1987, as many as 50 to 100 major system audits were conducted against customer or supplier standards in each month or over short periods in many companies .

The availability of the one series of standards and a uni-

fied certification system made a major impact. The problems caused by multiple audits against proprietary specifications are now in the distant past, this impact, very significant in its time, may not be fully appreciated today.

The availability of the ISO 9000 series has provided a dependable base on which industry-specific or sector-specific standards can be developed without confusing the generic base. Some examples are in laboratory accreditation, medical devices, automotive production and the food supply chain.

The drive to integrate quality with management systems and compatibility with standards in other fields was ably demonstrated in the 1990s and is currently a major impact point, allowing integra-

tion and compatibility of many functions within the overall management systems and processes without conflict, confusion or unnecessary costs.

The impacts of the ISO 9000 family of standards, from its development and implementation in the years 1979 through 1998, has set a reliable foundation for subsequent and future years as global trade increases. ●



ISO 9000 : a lot more than meets the eye



by **Pierre Caillibot**, Chair of
ISO/TC 176 from 1998 to 2002

I first participated in an ISO/TC 176 meeting as an expert in Working Group 2, before it became Subcommittee 2, in the old BSI (British Standards Institution) headquarters, in the early 1980s. My first ISO/TC 176 plenary was in Pretoria in 1984, and it was followed by two decades of continual participation.

Many have rightly extolled the direct contribution that implementing the ISO 9000 family of standards has made to trade facilitation, customer-supplier relationships, improved managerial performance of many thousands of organizations, as well as improved confidence and satisfaction of customers of these organizations.

I need not reiterate these results, which have been well reported. Instead, I would like to underline a contribution not so often highlighted.

Crucible

ISO/TC 176 has been, for over a quarter of a century, a crucible for developing an ever-increasing international consensus about quality concepts, principles and related good management practices. At the same time, ISO/TC 176 has also spearheaded a tremendously successful knowledge-sharing and training network.

To illustrate the vastness of this network, think of the hundreds of participants in all the working groups and subcommittees, as well as in the full committee plenaries of ISO/TC 176.

Add to that the thousands of participants in mirror committees in numerous countries and liaison bodies, as well as the many more thousands of people involved in implementing these standards or in evaluating implementation for contractual or certification purposes.

Multiply all this by the time invested by each of these participants, sometimes over the course of decades.

Finally, consider the interaction between ISO/TC 176 and the many industrial/economic sectors: automotive, aerospace, food, laboratories, etc. Although difficult to compare to the direct impact of the standards, this network has, in my opinion, also made a phenomenal contribution to the world. •

ISO/TC 176 is also
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knowledge-sharing
network

