Chapter 5
How ISO 9000 made us think about quality

A system, whether physical or metaphysical, commonly owes its success to its novelty; and is no sooner canvassed with impartiality than its weakness is discovered.

***David Hume** (1711–1776), Scottish philosopher*

Introduction

Although it is now six years since the publication of ISO 9000:2000, there is still a lot to be learnt from the way this standard has been used over the past 20 years. The lessons are not only applicable to ISO 9000. Whether you are contemplating using six sigma, balanced score card, TQM or any other approach to change, you may find that any new fad can generate the same perceptions and misconceptions as ISO 9000.

Also, for many organizations outside the engineering, food and medicines industries, ISO 9000 was their first encounter with quality management. Whereas quality control had been a feature of these industries since before 1960, for many it was not until they were exposed to ISO 9000 that they became aware that the principles, tools and techniques of quality management could be applied in any enterprise – but unfortunately ISO 9000 was not the ideal vehicle to do this.

Since the publication of the ISO 9000 family of standards in 1987 a new industry has grown in its shadow. The industry is characterized by Standards Bodies, Accreditation Bodies, Certification Bodies, Consulting Practices, Training Providers, Software Providers and a whole raft of publications, magazines, web sites and schemes – all in the name of quality! But has ISO 9000 and its derivates such as ISO/TS 16949 fulfilled its promise? There are those with vested interests that would argue that it has improved the efficiency and effectiveness of

organizations. Equally others would argue that it has done tremendous damage to industry. One of the problems in assessing the validity of the pros and cons of the debate is the very term ISO 9000 because it means different things to different people.

Perceptions that have been confirmed time and again by consultants, other organizations and frequent audits from the certification bodies over the last 20 years makes these perceptions extremely difficult to change. If ISO 9000 is perceived rightly or wrongly, as a badge on the wall or a set of documents, then that is what it is. If this was not the intent of ISO 9000 then clearly we have to do something about it. But why should these perceptions be changed? After all, can over 500,000 organizations have got it wrong? Some organizations in fact did use ISO 9000 wisely but they are likely to be in the minority. Many organizations also chose not to pursue ISO 9000 certification and focused on TQM but that too led to dissatisfaction with the results. It may be useful to take a look at these perceptions – look at how we have come to think about ISO 9000, quality, quality systems, certification and inspection. It is interesting to note that even those responsible for the standard recognized the weaknesses of the 1994 version.

Pierre F. Caillibot (Canada) Chairman of the ISO technical committee responsible for the ISO 9000 family of standards (TC 176) wrote in 2001[1] that "one of the main problems with the 1994 version was that it left the door open to confusion between ends and means, and could therefore lead to an unwanted degree of variability in understanding the minimum requirement threshold. Between the rationale for the standard and a minimalist interpretation of its contents, there was an embarrassing margin which was liable to damage its credibility."

A realization of these perceptions will hopefully enable us to approach the subject of quality management with a different perspective or at least provide food for thought.

How we think about ISO 9000

To the advocate, ISO 9000 is a standard and all the negative comments have nothing to do with the standard but the way it has been interpreted by organizations, consultants and auditors. To the critics, ISO 9000 is what it is perceived to be and this tends to be the standard and its support infrastructure. This makes any discussion on the subject difficult and inevitably leads to disagreement.

Some people often think about ISO 9000 as a system. As a group of documents, ISO 9000 is in fact a set of interrelated ideas, principles and rules and could therefore be considered a system in the same way that we refer to the metric system or the imperial system of measurement. ISO 9000 is both an international standard and until December 2000, was a family of some 20 international standards. As a standard, ISO 9000 was divided into four parts with Part 1 providing guidelines on the selection and use of the other standards in the family. The family of standards included requirements for quality assurance and

guidelines on quality management. Some might argue that none of these are in fact standards in the sense of being quantifiable. The critics argue that the standards are too open to interpretation to be standards – anything that produces such a wide variation is surely an incapable process with one of its primary causes being a series of objectives that are not measurable. Only ISO 8402 of the ISO 9000 family was invoked but this has changed with the 2000 version. However, if we take a broader view of standards, any set of rules, rituals, requirements, quantities, targets or behaviours that have been agreed by a group of people could be deemed to be a standard. Therefore, by this definition, ISO 9000 is a standard.

ISO 9000 is also perceived as a label given to the family of standards and the associated certification scheme. However, certification was never a requirement of any of the standards in the ISO 9000 family – this came from customers. Such notions as "We are going for ISO 9000" imply ISO 9000 is a goal like a university degree and like that there are those who pass who are educated and those who merely pass the exam. You can purchase degrees from unaccredited universities just as you can purchase ISO 9000 certificates from unaccredited certification bodies. The acceptance criteria is the same, it is the means of measurement and therefore the legitimacy of the certificates that differ.

As many organizations did not perceive they had a quality management system before they embarked on the quest for ISO 9000 certification, the programme, the system and the people were labelled "ISO 9000" as a kind of shorthand. Before long, these labels became firmly attached and difficult to shed and consequently why people refer to ISO 9000 as a "system".

How we think about quality management systems

All organizations have a way of doing things. For some it rests in the mind of the leaders, for others it is translated onto paper and for most it is a mixture of both. Before ISO 9000 came along, organizations had found ways of doing things that worked for them. We seem to forget that before ISO 9000, we had built the pyramids, created the mass production of consumer goods, broken the sound barrier, put a man on the moon and brought him safely back to earth. It was organizational systems that made these achievements possible. Systems, with all their inadequacies and inefficiencies, enabled mankind to achieve objectives that until 1987 had completely revolutionized society. The next logical step was to improve these systems and make them more predictable, more efficient and more effective – optimizing performance across the whole organization – not focusing on particular parts at the expense of the others. What ISO 9000 did was to encourage the formalization of those parts of the system that served the achievement of product quality – often diverting resources away from the other parts of the system.

ISO 9000 did require organizations to establish a quality system as a means of ensuring product met specified requirements. What many organizations

failed to appreciate was that they all have a management system – a way of doing things and because the language used in ISO 9000 was not consistent with the language of their business, many people did not see the connection between what they did already and what the standard required. People may think of the organization as a system, but what they don't do is manage the organization as a system. They fail to make linkages between actions and effects and will change one function without considering the effects on another. (Neither ISO 9000 nor its derivatives has brought about an improvement in this situation. However, the connectivity is emphasized in other approaches such as Process Management and Six Sigma.)

New activities were therefore bolted onto the organization such as management review, internal audit, document control, records control, corrective and preventive action without putting in place the necessary linkages to maintain system integrity. What emerged was an organization with warts as illustrated in Figure 5.1. This was typical of those organizations that merely pursued the "badge on the wall". Such was the hype, the pressure and the razzmatazz, that the part that was formalized using ISO 9000 became labelled as the ISO 9000 quality system. It isolated parts of the organization and made them less efficient. Other organizations recognized that quality was an important issue and formalized part of their informal management system. When ISO 14001 came along this resulted in the formalization of another part of their management system to create an Environmental Management System (EMS). In the UK at least, with the advent of BS 8800 on Occupational Health and Safety Management Systems (OHSMS), a third part of the organization's management system was formalized. The effect of this piecemeal formalization is illustrated in Figure 5.2. This perception of ISO 9000, ISO 14000 and any other management system standard is also flawed – but it is understandable.

The 1994 edition of the ISO 9000 family of standards was characterized by its focus on procedures. In almost every element of ISO 9001 there was a requirement for the supplier to establish and maintain documented procedures to control some aspect of an organization's operations. So much did this requirement

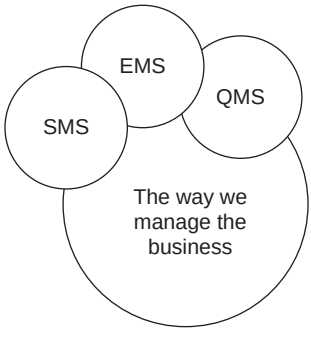

Figure 5.1 Bolt-on systems

Figure 5.2 Separate systems

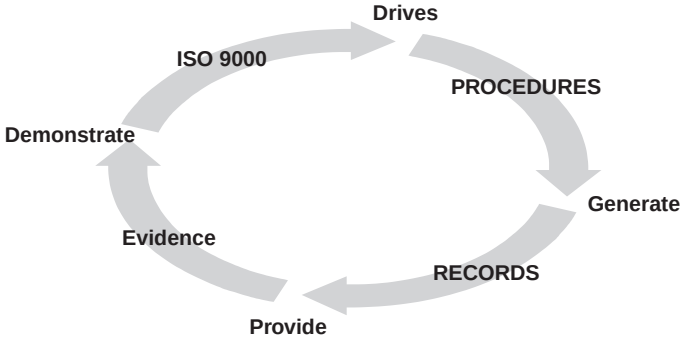

Figure 5.3 The conformity cycle

pervade the standard that it generated the belief that ISO 9000 was simply a matter of documenting what you do and doing what you document. This led to the perception that ISO 9000 built a bureaucracy of procedures, records and forms with very little effect on quality. What emerged was a cycle of conformity. Organizations started by reading the standard, producing procedures to comply with the standard and then generating records that were used as evidence to demonstrate compliance with ISO 9000 to external auditors. This is illustrated in Figure 5.3.

The 1994 version also created a perception that quality systems only exist to assure customers that product meets requirements. ISO 9001 was often referred to as a Quality Assurance standard because customers used it for obtaining an assurance of the quality of products being supplied. This perception is illustrated in Figure 5.4, in which the organization is represented as a circle containing islands that serve the assurance of quality and with the remainder of the organization running the business. This is one reason why Toyota terminated its ISO 9000 certification programme – it did not cover important aspects of the business such as cost management.

Assurance equates with provision of objective evidence and this equates with the generation and maintenance of documentation i.e. procedures and

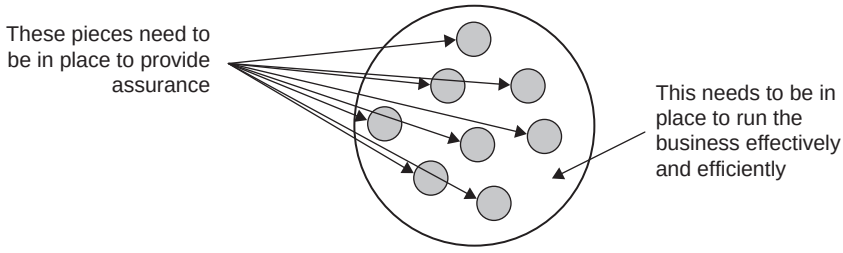

Figure 5.4 Separating assurance activities from management activities

records. With the pressure from auditors to show evidence, organizations were persuaded to believe that if it wasn't documented it didn't exist and this ultimately led to the belief that quality systems were a set of documents. These systems tended to be sets of documents that were structured around the elements of a standard. None of the standards required this, but this is how it was implemented by those who lacked understanding. However, ISO 9001 Clause 4.2.1 required suppliers to establish a quality system to ensure (not assure) that product met specified requirements. In other words, it required the system to cause conformity with requirements. A set of documents alone cannot cause product to conform to requirements. When people change the system they invariably mean that they update or revise the system documentation. When the system is audited invariably it is the documentation that is checked and compliance with the standard verified. There is often little consideration given to processes, resources, behaviours or results. As few people seem to have read ISO 8402, it is not surprising that the documents are perceived as a system. (Note: In talking with over 600 representatives of UK companies in 1999 and 2000 the author discovered that less than 10% had read ISO 8402.) But ISO 8402 defined a system rather differently. A quality system was defined as *the organization structure, procedures, processes and resources needed to implement quality management* – clearly not a set of documents. The 1994 version required a system to be established and documented. If the system was a set of documents, why then require it to be established as well as documented? (We have no evidence to show that the authors understood the difference so it is rather patronizing to speculate that they did!)

The persistence of the auditors to require documentation led to situations where documentation only existed in case something went wrong – in case someone was knocked down by a bus. While the unexpected can result in disaster for an organization it needs to be based on a risk assessment. There was often no assessment of the risks or the consequences. This could have been avoided simply by asking the question "so what?" So there are no written instructions for someone to take over the job but even if there were, would it guarantee there were no hiccups? Would it *ensure* product quality? Often the new person sees improvements that the previous person missed or deliberately

chose not to make – often the written instructions are of no use without training and often the written instructions are of no value whatsoever.

There has also been a perception in the service industries that ISO 9000 quality systems only deal with the procedural aspects of a service and not the professional aspects. For instance in a medical practice, the ISO 9000 quality system is often used only for processing patients and not for the medical treatment. In legal practices, the quality system again has been focused only on the administrative aspects and not on the legal issues. The argument for this is that there are professional bodies that deal with the professional side of the business. In other words, the quality system only addresses the non-technical issues, leaving the profession to address the technical issues. This is not *quality management*. The quality of the service depends on both the technical and non-technical aspects of the service. Patients who are given the wrong advice would remain dissatisfied even if their papers were in order or even if they were given courteous attention and advised promptly. To achieve quality one has to consider both the product and the service. A faulty product delivered on time, within budget and with a smile remains a faulty product!

How we think about certification

Pressure for certification

When an organization chooses not to pursue ISO 9000 certification or not to retain the ISO 9000 certificate, it should make no difference to the way the organization is managed. It's similar to the man who chooses not to take the course examination. He still has the knowledge he has acquired whether or not he takes the examination and gets a certificate. What he cannot do is demonstrate to others that he has reached a certain level of education without having to prove it every time. People who know him don't care that he didn't take the examination. It is only those who don't know him that he will have difficulty convincing.

A historical perspective

ISO 9000 came out of the defence industry where there was a long tradition of command and control. It followed the same pattern of imposing requirements to prevent failures that experience had shown led to poor product quality.

Many organizations were driven to seek ISO 9000 certification by pressure from customers rather than as an incentive to improve business performance and therefore sought the quickest route to certification. The critics called this coercion and like most command and control strategies, believed it resulted in managers cheating just to get the badge. What was out of character was that suppliers that were well known to customers were made to jump through this hoop in order to get a tick in a box in a list of approved suppliers. It became a "necessary evil" to do business. Certainly when perceived as a means to get a badge, the standard

was no more than a marketing tool. It could have been used as a framework for improvement but the way it was imposed on organizations generated fear brought about by ignorant customers who mistakenly believed that imposing ISO 9000 would improve quality. To achieve anything in our society we inevitably have to impose rules and regulations – what the critics regard as *command and control* – but unfortunately, any progress we make masks the disadvantages of this strategy and because we only do what we are required to do, few people learn. When people make errors more rules are imposed until we are put in a straightjacket and productivity plummets.

ISO 9001 Certification is not a requirement of any of the standards in ISO 9000 family, nor is it encouraged by the standard. It is however encouraged by governments and this is where the misunderstanding arises. Governments encouraged organizations to use ISO 9000 alongside product standards in their purchasing strategy so as to raise the standard of quality in national and international trade.[2] Certification became a requirement of customers – they mandated it through contracts. ISO 9000 was a convenient standard to use in order for customers to gain an assurance of quality. ISO 9000 was launched at a time when customers in the western world took an adversarial approach to their suppliers. ISO 9000 did not require purchasers to impose ISO 9000 on their suppliers. What it *did* require was for purchasers to determine the controls necessary to ensure whether purchased product met their requirements. But the easy way of meeting this requirement was to impose ISO 9000. (Unfortunately this approach is being used in the automotive industry where 2nd, 3rd, or 4th tier suppliers are being coerced into getting ISO/TS 16949 certification.) It saved the purchaser from having to assess for themselves the capability of suppliers. Unfortunately the assessment process was ineffective because it led to suppliers getting the badge that were not capable of meeting their customer's requirements. ISO 9001:1994 required suppliers to establish a quality system to ensure that product met specified requirements but it allowed organizations to specify their *own requirements* – provided they did what they said they did, they could receive the certificate. As there were no specific requirements in the standard that caused the auditors to verify that these requirements were those needed to meet the needs and expectations of customers, organizations could produce rubbish and still receive the badge. What was being checked was *consistency* – not *quality*.

Before ISO 9000, organizations were faced with meeting all manner of rules and regulations. Government inspectors and financial auditors frequently examined the books and practices for evidence of wrong-doing but none of these resulted in organizations creating something that was not integrated within the routines they applied to manage the business. When ISO 9000 came along, many organizations embarked on a course of action that was perceived to have no value except to keep the badge – the ISO 9000 certificate. Activities were only documented and performed because the standard required it. Take away the

certification and there was no longer a business need for many of these procedures and activities.

ISO 9000-1:1994 in fact suggested that there were two approaches to using ISO 9000: "management-motivated" and "stakeholder-motivated". It suggested that the supplier should consult ISO 9000-1 to understand the basic concepts but few organizations did this. It also suggested that with the management-motivated approach organizations should firstly design their systems to ISO 9004-1 and then choose an appropriate assessment standard. In addition it suggested that with the stakeholder-motivated approach an organization should initially implement a quality system in response to the demands of customers and then select ISO 9001, ISO 9002 or ISO 9003 as appropriate for assessment. It suggested that having found significant improvements in product quality, costs and internal operating results from this approach, the organization would initiate a management-motivated approach based on ISO 9004. Those suppliers that actually obtained such benefits no doubt did initiate a management-motivated approach but many only focused on getting a certificate and therefore did not gain any benefits apart from the marketing advantage that ISO 9000 certification brought.

This eminently sensible approach has been changed in the ISO 9000:2000 family of standards. It is now suggested that, "beginning with ISO 9000:2000, you adopt ISO 9001:2000 to achieve a first level of performance. The practices described in ISO 9004:2000 may then be implemented to make your quality management system increasingly effective in achieving your own business goals."[3] It must be said that it is a retrograde step to place ISO 9004 in the role of being a tool for system improvement rather than system development and improvement, although when one examines the text of ISO 9004 it clearly contains guidance on both system development and improvement.

The approach to certification

Believing that ISO 9000 was only about "documenting what you do", organizations set to work on responding to the requirements of the standard as a list of activities to be carried out. Again, this belief became so widespread that ISO co-ordinators or ISO 9000 project managers were appointed to establish and maintain the quality system. In some organizations, managers were assigned responsibility for meeting the requirements of a particular element of the standard even though there was not only no requirement to do so, but also no business benefit from doing so. Consultants were engaged to write the documents and apart from some new procedures governing internal audits, management review and document control, very little changed. There was a lot of money thrown at these projects in the quest to gain certification. However, none of the surveys conducted since 1987 have shown any significant improvement in an organization's overall performance – quite simply because nothing changed,

not the processes, not the people nor the culture. The "system" existed just to keep the badge on the wall. The ninth ISO survey[4] indicated that 9,862 certificates had been withdrawn at the end of 1999 and of these 473 were for reasons of either insufficient return on investment or no business advantage. However some 7,186 organizations discontinued certification for reasons unknown, indicating that certification was probably perceived as not adding value.

The approach to auditing

To make matters worse, the certification scheme established to assess the capability of organizations perpetuated this belief. These third party auditors would reinforce the message by commencing their interviews with the question "Have you got a procedure for . . . ?" Audits would focus on seeking evidence that the organization was implementing its procedures. This technique was not limited to ISO 9001 assessments, it also pervaded assessments against ISO 9000 derivatives. Desperate to put the "badge on the wall" organizations responded to the auditor's expectations and produced quality manuals that mirrored the structure of the standard – manuals containing nothing more than the requirements of Section 4 of ISO 9001 or ISO 9002, reworded as policy statements. The auditor would therefore establish an organization's readiness for the audit by the closeness with which the quality manual addressed the requirements of the standard rather than by examining performance. A more sensible approach might have been to ask for the last 3 months data for the key processes to establish if the processes were stable.

Instead of using the whole family of standards as a framework, the standards became a stick with which to beat people. Managers would ask, where does it say that in the standard and if the auditor or consultant could not show them, the manager did nothing. The astute manager would ask, "Why would I want to do that?" and if the auditor or consultant could not give a sound business case for doing it, the manager did nothing.

Auditor training

Customers of auditor training courses behaved as though all they wanted was a training certificate. This led to lower standards. The auditors were poorly trained and the trainers became a victim of the system. Rules forced training bodies to cover certain topics in a certain time. Commercial pressure resulted in training bodies cutting costs to keep the courses running. Customers would not pay for more than they thought they needed but they did not know what they needed. Tell them what is required to convert a novice into a competent auditor and they wince! When there are providers only too willing to relieve them of their cash, customers opt for the cheaper solution. Had customers of training course been purchasing a product that failed to function there would have been an outcry, but the results of training were less likely to be measured. The training

auditors received focused on auditing for conformity and led to auditors learning to catch people out. It did not lead to imparting the skills necessary for them to conduct audits that added value for organizations.

The effect of competition

Certification bodies were also in competition and this led to auditors spending less time conducting the audit that was *really* needed. They focused on the easy things to spot and not on whether the system was effective. Had the provision of certification services not been commercialized, there would not have been pressure to compromise quality. Organizations stayed with their certification body because they gave them an easy ride. What certification body would deliberately do things to lose customers? They will do everything they can to keep customers – even if it means turning a blind eye. Certification bodies were also barred from making suggestions on improvement because it was considered to be consulting. They therefore stuck to familiar ground. The accreditation bodies were supposed to be supervising the certification bodies but they also needed revenue to be able to deploy assessors in sufficient numbers to maintain the integrity of the certification scheme. It had to be commercially viable at the outset otherwise the whole certification scheme would not have got off the ground because governments would not have been prepared to sponsor it. It is interesting that in the UK, there has been considerable protest against privatising the National Air Traffic Service for fear that profits will compromise air space safety. There was no outcry against commercially operated quality system certification but equally unsafe products could emerge out of an ineffective quality system and enter the market. Certification in the automotive sector is somewhat different where an industry led accreditation and witness audit scheme operates that might just make third party audits less prone to abuse.

Misplaced objectives

The certification scheme also added another dimension – that of scope. The scope of certification was determined by the organization so that only those parts of the quality system that were in the scope of certification were assessed. The quality system may have extended beyond the scope of certification and the scope of the standard but been far less than the scope of the business. This is illustrated in Figure 5.5.

Food for thought

Is our goal to survive the audit or to improve our performance?

Quality managers scurried around before and after the assessor and in doing so led everyone else to believe that all that was important to the assessor was documentation. This led others in the organization to focus on the things the auditor looked for not on the things that mattered – they became so focused on satisfying the auditor that

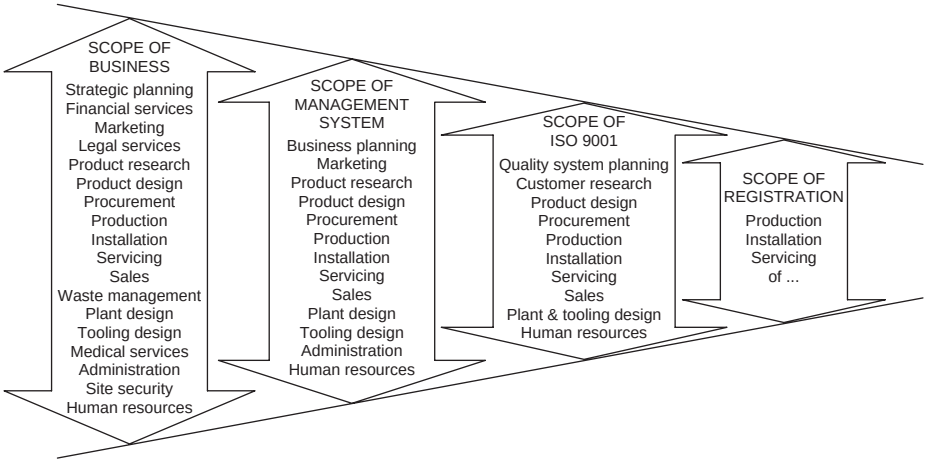

Figure 5.5 The scoping effect

they lost sight of their objectives. They focused on surviving the audit and not on improving the performance. It has the same effect as the student who crams for an examination. The certificate may be won but an education is lost. What would the organization rather have – a certificate or an effective management system? Organizations had it in their power to terminate the contract with their Certification Body if they did not like the way they handled the assessment. They had it in their power to complain to the Accreditation Body if they were not satisfied with the service rendered by the Certification Body but on both counts they failed to take any action. Certification Bodies are suppliers, not regulators. What went wrong with ISO 9000 assessments is that the auditors lost sight of the objective to improve the quality of products and services. They failed to ask themselves whether the discrepancies they found had any bearing on the quality of the product. Many of the nonconformities were only classified as such because the organization had chosen to document what it did regardless of its impact on quality. Auditors often held the view that if an organization took the trouble to document *it*, *it* must be essential to product quality and therefore by not doing *it*, product quality must be affected!

How ISO 9000 made us move our eye off the ball

ISO 9000 was conceived to bring about an improvement in product quality. It was believed that if organizations were able to demonstrate that they were operating a quality system that met international standards, customers would gain greater confidence in the quality of products they purchased. It was also believed that by operating in accordance with documented procedures, errors would be reduced and consistency of output ensured. If you find the best way of achieving a result, put in place measures to prevent variation, document it and

train others to apply it, it follows that the results produced should be consistently good. But it didn't work that way, primarily because organizations did not understand that processes are different from procedures.

The requirements of the standard were perceived to be a list of things to do to achieve quality. The ISO co-ordinator would often draw up a plan based on the following logic:

- We have to identify resource requirements so I will write a procedure on identifying resource requirements.
- We have to produce quality plans so I will write a procedure on producing quality plans.
- We have to record contract reviews so I will write a procedure on recording contract reviews.
- We have to identify design changes so I will write a procedure on identifying design changes.

The requirements in the standard were often not expressed as results to be achieved. Requirements for a documented procedure to be established resulted in just that. Invariably the objectives of the procedure were to *define something* rather than to *achieve something*. This led to documentation without any clear purpose that related to the achievement of quality. Those producing the documentation were focusing on meeting the standard not on achieving quality. Those producing the product were focusing on meeting the customer requirement but the two were often out of sync. As quality assurance became synonymous with procedures, so people perceived that they could achieve quality by following procedures. The dominance of procedures to the exclusion of performance is a misunderstanding of the implementers. The standard required a documented system *that ensured product met specified requirements* thereby indicating a clear purpose. Once again the implementers lost sight of the objective. Or was it that they knew the objective but in order to meet it, the culture would have to change and if they could get the badge without doing so, why shouldn't they?

Issuing a procedure was considered to equate to the task being completed. Unfortunately, for those on the receiving end, the procedures were filed and forgotten. When the auditor came around, the individual was found to be totally unaware of the "procedure" and consequently found noncompliant with it. However, the auditor would discover that the individual was doing the right things so the corrective action was inevitably to change the procedure. The process of issuing procedures was not questioned, the individual concerned was blamed for not knowing the procedure and the whole episode failed to make any positive contribution to the achievement of quality. But it left the impression on the individual that quality was all about following procedures. It also left the impression that quality was about consistency and providing you did what you said you would do regardless of it being in the interests of satisfying customers, it

was OK. One is left wondering whether anyone consulted the dictionary in which quality is defined as *a degree of excellence*?

Another problem was that those who were to implement requirements were often excluded from the process. Instead of enquiring as to the best way of meeting this requirement, those in charge of ISO 9000 implementation assumed that issuing procedures would in fact cause compliance with requirements. It requires a study of the way work gets done to appreciate how best to meet a requirement. Procedures were required to be documented and the range and detail was intended to be appropriate to the complexity of the work, the methods used and the skills and training needed. The standard also only required work instructions where their absence would adversely affect quality. It is as though the people concerned did not read the requirement properly or had no curiosity to find out for themselves what ISO had to say about procedures – they were all too ready to be told what to do without questioning why they should be doing it.

More often than not, the topics covered by the standard were only a sample of all the things that need to be done to achieve the organization's objectives. The way the standard classified the topics was also often not appropriate to the way work was performed. As a consequence, procedures failed to be implemented because they mirrored the standard and not the work. ISO 9000 may have required documented procedures but it did not insist that they should be produced in separate documents, with titles or an identification convention that was traceable to the requirements. Unfortunately this insistence of documented procedures has not subsided entirely. There are still six mandatory documented procedures required by ISO 9001:2000 indicating a complete lack of imagination. They could have eliminated all requirements for documented procedures had they required a risk assessment be carried out.

Critics argue[5] that ISO 9000 did not enable organizations to reduce variation as a result of following the procedures. It is true that ISO 9000 did not explain the theory of variation – it could have done, but perhaps it was felt that this was better handled by the wealth of literature available at the time. However, ISO 9000 did require organizations to identify where the use of statistical techniques was necessary for establishing, controlling and verifying process capability but this was often misunderstood. Clause 4.14 of ISO 9001 required corrective action procedures – i.e. procedures to identify variation and eliminate the cause so this should have resulted in a reduction in variation. The procedures did not always focus on results – they tended to focus on transactions – sending information or product from A to B. The concept of corrective action was often misunderstood. It was believed to be about fixing the problem and preventive action was believed to be about preventing recurrence. Had users read ISO 8402 they should have been enlightened. Had they read Deming they would have been enlightened but in many cases the language of ISO 9000 was a deterrent to learning. Had the auditors understood variation, they could have

assisted in clarifying these issues but they too seemed ignorant – willing to regard Clause 4.20 as not applicable in many cases. But in the automotive industry, things were different. SPC and process capability studies had been part of the quality programmes for many years, although these techniques were often only applied to the production line.

Clause 4.6 of the undervalued and forgotten standard ISO 9000-1 dated 1994, starts with "The International Standards in the ISO 9000 family are founded upon the understanding that all work is accomplished by a process". In Clause 4.7 it starts with "Every organization exists to accomplish value-adding work. The work is accomplished through a network of processes". In Clause 4.8 it starts with "It is conventional to speak of quality systems as consisting of a number of elements. The quality system is carried out by means of processes which exist both within and across functions". Alas, few people read ISO 9000-1 and as a result the baggage that had amassed was difficult to shed especially because there were few if any certification bodies suggesting that the guidance contained in ISO 9000-1 should be applied. Unfortunately, this message from ISO 9000-1 was not conveyed through the requirements of ISO 9001 and also ISO 9001 was not intended as a design tool. It was produced for contractual and assessment purposes but was used as a design tool instead of ISO 9000-1 and ISO 9004-1.

How we think about reviews, inspections and audits

Audits of the quality system were supposed to determine its effectiveness but effectiveness seemed to be judged by the extent to which procedures were being followed. ISO 9001 Clause 4.1.3 did state that *the system should be reviewed for its continuing suitability and effectiveness in satisfying the requirements of the standard and the supplier's quality policy and objectives.* The words underlined were added in the 1994 revision. Clause 4.17 did require internal audits to *verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system*. Again the words underlined were added in the 1994 revision. But the original and modified wording seemed to have had no effect. Quality systems continued to be judged on product nonconformities, audit findings and customer complaints.

The management review was supposed to question the validity of these procedures, the validity of the standards and the performance of the system. It was supposed to determine whether the system was effective – i.e. whether the system enabled people to do the right things right. But effectiveness was not interpreted as doing the right things; it was interpreted as conforming to the standard. It led to quality being thought of as conformity with procedures. The reviews and audits therefore focused on deficiencies against the requirements of the standard and deviations from procedure rather than the results the system was

achieving. But as the system was not considered to be the way the organization achieved its results, it was not surprising that these totally inadequate management reviews continued in the name of keeping the badge on the wall. Audits did not establish that people were doing the right things – had they done so the system would have been changed to one that *caused people to do the right things right without having to be told*.

Food for thought

Has your management chosen a policy of not delegating authority for accepting results to those who produce them or is it the policy to assign responsibly for acceptance on the basis of a risk assessment?

It was often thought that the standard required review, approval, inspection and audit activities to be performed by personnel independent of the work. Critics argue that as a consequence both worker and inspector assumed the other would find the errors. ISO 9000 does not require independent inspection. There is no requirement that prohibits a worker from inspecting his or her own work or approving his or her own documents. It is the management that chooses a policy of not delegating authority for accepting results to those who produce them. There will be circumstances when independent inspection is necessary either as a blind check or when safety, cost, reputation or national security could be compromised by errors. What organizations could have done, and this would have met ISO 9000 requirements, is to let the worker decide on the need for independent inspection except in special cases. Alternatively they could have carried out a risk assessment and imposed independent inspection where the risks warranted it. However, inspection is no substitute for getting it right first time and it is well known that you cannot inspect quality into an output if it was not there to begin with.

Is ISO 9000:2000 any different?

There are those who want to believe that the standard has not changed very much (if at all) and do not believe it has changed in its intent and as a consequence do not have to change their approach. The sad thing is that if the standard is perceived as not having significantly changed, it will continue to wreak havoc by being interpreted and used in the same inappropriate way that it has been for the last 20 years. But there is another way. By looking at ISO 9000 as a framework on which can be built a successful organization (rather than as a narrow set of minimum requirements) significant benefits can be gained. There are real benefits from managing organizations as a set of interconnected processes focused on achieving objectives that have been derived from an understanding of the needs of customers and other stakeholders.

While the requirements of ISO 9001 are expressed in a way that takes the reader through a cycle starting with the organization's purpose, leading onto quality policy and quality objectives and ending with performance being reviewed against objectives, there remain many inconsistencies and distractions that could lead to

confusion. Many of the linkages between purpose, policy, objectives, processes and results are inferred – they are not expressed unambiguously. It is only by searching for understanding that a clear logic emerges. The use of the word *quality* creates an anomaly and tends to represent the standard as simply a tool to meet customer product or service quality requirements and no others. This is not to say that the standard is flawed. It is only saying that the concepts could be presented more clearly.

Misconceptions about the ISO 9000 family

Various misconceptions exist about the ISO 9000 family of standards. All of the following are untrue:

1. Products can be certified against ISO 9001. (Only organizations can be certified as compliant with ISO 9001.)
2. ISO 9001 is a management system. (Although the title of clause 0.3 of ISO 9001 is "Compatibility with other management systems" it is not intended to imply that ISO 9001 is a management system – ISO 9001 is a document not a system.)
3. The standard requires that you say what you do, do what you say and prove it. (A system needs to be established that enables the organization to satisfy the requirements of its customer and other stakeholders.)
4. The quality management system is the quality manual, procedures, instruction and records. (The quality manual, procedures, instruction and records is simply a description of the system – the system is that which generates the results, that which produces the outputs, that satisfy the stakeholders.)
5. Only 6 documented procedures are required. (The number of procedures required are those that are deemed necessary for the effective control and operation of the organization's processes.)
6. Process mapping is required for all processes. (The documentation can be in any form or medium. Processes need to be defined and documented to the extent necessary for effective operation and control.)
7. You have to appoint a Quality Manager. (A person needs to be appointed to ensure the system is established, implemented and maintained – what the job title is, is for the organization to decide.)
8. Job descriptions are required. (The responsibilities, authority and competences need to be defined – what the document is titled is for the organization to decide.)
9. All out of date documents have to be removed. (Obsolete documents may be retained if clearly identified as such.)
10. All purchases have to be from approved suppliers. (Suppliers need to be capable of meeting the organization's requirements.)
11. Purchase orders must be signed. (Orders need to be passed through a process that will ensure their adequacy prior to release.)

12. Documents have to carry an approval signature. (Documents need to be passed through a process that will ensure their adequacy prior to release.)
13. All measurements have to be made with calibrated instruments. (Measurement methods need to produce results of an accuracy and precision consistent with the measurement requirements.)

Summary

In this chapter we have examined the various perceptions about ISO 9000 and its infrastructure. These have arisen from personal observation, discussion with clients and colleagues and studying John Seddon's contribution in – *The Case Against ISO 9000*.

Wherever appropriate the perceptions are challenged from a basis of what the standard actually requires. This is no excuse for the resultant confusion. The standard could have been better written but it is unfair to put all the blame on the standard. The standards bodies, certification bodies, accreditation bodies, training providers, consultants, software providers and many others have contributed to this confusion. Commercial interests have as usual compromised quality. We have followed like sheep, pursued goals without challenging whether they were the right goals but most of all we have forgotten why we were doing this. It was to improve quality, but clearly it has not.

ISO 9000 merely brings together concepts that have been applied in organizations for many years – not some unique concepts of management that only exist to put a "badge on the wall", but it appears that the use of international standards to consolidate and communicate these concepts has not been as effective as we believed it would be. The BNFL problems with fake quality control records, the Firestone problem with unqualified materials, the SA 80 rifle that jams in cold weather, laser guided bombs that miss the target and the spate of problems with the railways in the UK all send the signal that we have not solved the problem of effectively managing quality. This is despite ISO 9000 and the teachings of Juran, Deming, Feigenbaum, Ishikawa, Crosby and the latest fad Six Sigma. ISO 9000:2000 is unlikely to change this situation because all these problems are caused by people who for one reason or another chose not to do the right things. All we can hope for is that people will learn from the mistakes of the past, use the family of standards more intelligently and raise the bar enough to enable more organizations to satisfy more customers and do less harm to society.

ISO 9000 has been influenced by disparate interests and thus is watered down, disjointed and tainted. An approach to the management of quality that has escaped this kind of treatment is process management and is presented in the next chapter. It is not yet the subject of national or international standards but many of the principles were adopted in the revision of ISO 9000. It is an approach that has yet to reach maturity.