

Chapter 1

A BRIEF HISTORY OF ISO 9000

WHERE DID WE GO WRONG?

During World War 2 we had a problem - bombs were going off in the factories. To solve the problem the UK's Ministry of Defence based inspectors in factories that supplied munitions. If you wanted to be a supplier, you had to write down the procedures for making your product, you had to ensure that your workers worked to these procedures by inspecting their work and finally you had to have this whole method of working inspected by a Government inspector. From this seed, a whole forest of control and inspection has grown in the name of quality.

This was a way of working which ensured that production met specifications. It was a method of control that was designed to ensure consistency of output. The inherent logic was quite straightforward and remains appealing – you control how you do the work and hence you make what you say you are going to make. These ideas solved a problem of the time – bombs stopped going off in factories (1). Whether they went off when they should, whether they were better quality bombs, was another matter. “Quality” became associated with “conformance” rather than “improvement” and “quality assurance” implied that “conformance had been assured” through inspection.

The development of quality standards reflected the desire to shift the burden of work from inspection by Government inspectors (second party inspection) to “quality assurance” guaranteed by the supplier through third party inspection. In 1959 the United States developed Mil-Q-9858a (“Quality Program Requirements”), their first quality standard for military procurement. It laid down what suppliers had to do to achieve conformance. By 1962 the NASA space programme had also developed its “quality system requirements” for suppliers.

All of this effort reflected a genuine and serious concern. Many of our new technologies were causing us unfortunate problems. In 1962, Vice Admiral Rickover of the US Navy summarised the situation (2). He spoke openly about what was happening in the nuclear industry. Things were going wrong; there had been a series of problems and as the US Naval Reactors Programme grew in scope, things were getting worse rather than better. To quote his opening remarks:

“Progress – like freedom – is desired by nearly all men, but not all understand that both come at a cost. Whenever society advances...there is a rise in the requirements man must meet to function successfully.”

In short, he was concerned that the new nuclear technology was insufficiently understood and thus there were associated risks. To quote two later passages of his speech:

“Unfortunately decisions affecting this field are sometimes made by people who have little knowledge of nuclear engineering and of science. There is a danger this will lead to errors highly damaging to the position of the United States or to the health and safety of the American people.”

“Too often management is satisfied to sit in plush offices, far removed physically and mentally from the design and manufacturing areas, relying on paper reports for information about the status of design and production in the plant itself – the real centre of the enterprise. This lack of first-hand evaluation results in poorly designed and manufactured equipment, late delivery, or both. During the past few years, hundreds of major conventional components, such as pressure vessels and steam generators, have been procured for naval nuclear propulsion plants. Less than ten percent have been delivered on time. Thirty percent were delivered six months to a year or more later than promised. Even so, re-inspection of these components after delivery showed that over fifty percent of them had to be further re-worked in order to meet contractual specification requirements.”

These problems were not unique to the US military. In the UK, during the 1950s and 1960s, we were experiencing similar problems in all of the new industries. For example in the power industry we had failures of turbine blades and boilers. Our nuclear industry was experiencing similar problems to those in America. These were problems associated with progress. Something had to be done and quality assurance seemed, to many, to be the answer. In 1968 NATO adopted the AQAP (Allied Quality Assurance Procedures) specifications – standards for the procurement of NATO equipment. The UK Government was, naturally, a signatory.

By this time, the idea of quality assurance had spread beyond the military. In 1969 the UK's Central Electricity Generating Board and Ontario Hydro in Canada developed quality assurance standards for suppliers. Earlier, in 1966, the UK Government led the first national campaign for quality and reliability with the slogan “quality is everybody's business”. In the report of the year [\(3\)](#), the following observations were made:

“The vital role of large purchasers – and the beneficial ‘ripple effect’ they can stimulate among their suppliers; their influences, through vendor rating and supplier quality assurance schemes, can help greatly to raise the level of quality procedures throughout industry. Consideration, however, could well be given to a more co-ordinated system of vendor rating to avoid the multiplicity of assessments made by each customer.”

At this time, suppliers were being assessed by any and all of their customers. It was widely recognised that this was very wasteful, duplicating effort and consuming resources unnecessarily. In 1969 Colonel G W Raby chaired a committee whose task was to report on the inspection and assessment of the UK's military quality systems. His committee report reinforced the idea that suppliers should take responsibility for quality assurance and recommended that their methods should be

assessed against generic standards of quality assurance. This was to open the door to third party inspection; it would lead to the establishment of assessing organisations. It would also lead to the wholesale redundancy of many Government (second party) assessors during the early 1970s. These people were to populate the new assessing and consulting organisations, which were to grow rapidly.

These first standards for quality assurance were thought of as contractually binding obligations. During the 1970s the debate moved to how best to inspect and assure. Some commentators favoured a national body that would have responsibility for assessment of suppliers; industry was not so keen on the idea (4). Meanwhile, in 1971 the British Standards Institute (BSI) published the first UK standard for quality assurance – BS 9000, which was developed for the electronics industry in response to the many problems that were occurring in this, another new industry. In 1974 BSI published BS 5179, “Guidelines for Quality Assurance”; the BSI was the natural home for the quality assurance debate and its leaders at the time were fully involved in the developing assurance industry.

The UK Government was also very involved. Beyond the sponsorship of the “Quality and Reliability Year” in 1966, the Government had management responsibility for many of the new industries. Half the UK workforce was employed in Government owned or Government subsidised industry. Power generation and distribution, extraction of natural resources, telecommunications and even automotive manufacturing were in Government’s hands. It was in the Government’s interest to do something to improve things. The Government also employed some 17,000 inspectors. The solution, when it came, must have appeared very attractive – at the same time as releasing thousands of people, Government could claim to be promoting the improvement of British industry.

During the 1970s BSI orchestrated meetings of the many interested parties in order to agree a common British standard. The result was the publication of BS 5750 in 1979. Key industry bodies, that had developed contractual documents for suppliers, agreed to drop their own standards and reference BS 5750 instead. In keeping with the historical perspective, the purpose of BS 5750 was to provide a common contractual document, demonstrating that production was controlled. This standard had nothing to do with methods for performance improvement. This shift in emphasis and the problems it spawned were to come later.

What were the key elements of BS 5750?

They can be summarised as follows:

Management responsibility: Management should define and document a quality policy, an organisation structure, including responsibility and authority. Management should make available verification resources (inspectors), appoint a management representative and carry out management reviews.

Quality system: The quality system must be documented, including a manual, procedures and work instructions.

Contract review: A procedure for performing contract review – documenting what was agreed with the customer – should be written stating clearly the criteria for contractual obligations to be met.

Design control: Procedures should define how the organisation designs its product and controls any design changes.

Document control: Procedures and work instructions must be approved before issue and on subsequent changes. Control of documents should encompass availability, distribution, issue level, revision and obsolescence.

Purchasing: Suppliers should be assessed and monitored, incoming goods should be verified.

Customer supplied stock: Customer supplied stock should be subject to procedures for identification, inspection, storage and periodic maintenance. There should also be a procedure for reporting and recording lost or damaged stock.

Product identification and traceability: A company-wide procedure should detail how items and equipment are to be identified at all stages from receipt to despatch. Where traceability is required, a unique identification should be used and recorded.

Process control: Work instructions defining what is done should be documented and made available.

Inspection and test: Inspection should be performed on receipt of goods. Documented procedures should define the appropriate tests. Tests should be performed for repair or service to demonstrate restoration of operative condition. Records should provide evidence to demonstrate the equipment or device meets the necessary inspection or test criteria.

Inspection, measuring and test equipment: These must be controlled, calibrated and maintained.

Inspection and test status: This must be identified by using markings, stamps, labels, routing documents, inspection/test record sheets, physical location or other suitable means.

Control of non-conforming product: Procedures must define the controls used to prevent the use of non-conforming product. Items should be identified, segregated and the authority for disposition made clear.

Corrective action: A corrective action procedure must be documented defining what is to be analysed, how corrective actions are to be initiated and obtained to prevent

re-occurrence. Corrective action procedures should be documented for dealing with customer complaints.

Handling, storage, packaging and delivery: There must be procedures for all of these. Additionally, inventory must be controlled and procedures for warranty must be written and communicated to customers.

Quality records: Procedures for identification, collection, indexing, filing, storage and maintenance must be written and records must be kept.

Internal quality audits: These must be planned and scheduled to verify the effectiveness of the quality system. Audits must be performed by staff independent of the authority responsible for the area being audited. The procedures for audits, follow-up actions and reporting must be documented.

Training: Procedures should be established to identify training needs. Training must be conducted on a formal basis and records kept.

Servicing: If there is a requirement to service equipment, the servicing procedures should be documented and maintained.

Statistical techniques: Statistical techniques should be used where appropriate.

BS 5750 was, in its essential content, no different from the methods used to stop bombs going off in factories. It was a method for the control of output. In response to the obvious problems we were having with our new technologies, this way of working was assumed to be a solution. At the end of the Seventies the standards movement had gained momentum. But its underlying theory was not good theory. While Vice Admiral Rickover – and many commentators since – lamented the state of management, this solution was to promote a theory of control, not a better theory of management. Perhaps we now have the benefit of hindsight, but would it not have been better to promote understanding rather than control? Admiral Rickover, discussing nuclear technology, saw management *understanding* as the priority:

“More effective management and engineering attention should be given to the routine and conventional aspects of our technology. Nothing must ever be taken for granted. Management must get into the details of problems... analyse the cause of trouble by personal investigation, and take prompt action to prevent recurrence... Management and engineers must not conclude their job is over once drawings have been completed and the first component successfully built and tested to these drawings.”

It is ironic that ISO 9000, what we would describe as the “control solution” to our problems, separated “design” from “process” (see page 137), making the understanding of this important issue less likely. It also served to maintain the

tradition that management could and should be separated from work (see page 62), something Admiral Rickover, rightly in our view, saw as the nub of the problem.

He went on:

“It should be of concern to us that specifications are normally written by manufacturers and therefore usually represent the lowest standard of engineering to which all manufacturers are willing to agree. This should be changed.”

However, ISO 9000 ensured that it was not. ISO 9000 ensured that the manufacturer could determine its own quality system, provided it also satisfied the requirements of an inspector.

And he concluded:

“Quality control must be recognised as an essential tool to enable management to meet today’s technological imperatives.”

But he did not say by what method. Admiral Rickover’s address was probably the most open account of our failures with new technologies. The undisputed truth and alarming nature of the problems he described fuelled the urgency to “do something”.

The same sense of urgency was being felt in British Government. In 1982 the Department of Trade and Industry published a white paper entitled “Standards, Quality and International Competitiveness” (5). It was to give a strong fillip to the emerging standards industry. Not only did it repeat many of the assertions of the leaders of the standards movement; it gave power to the BSI through a memorandum of agreement. The BSI now had Government backing to promulgate the adoption of the quality standard as quickly as possible and was authorised to represent the UK’s approach on the world stage. The white paper also set out the arrangements for “certification schemes” and hence created the inspection industry we know today.

Again, with hindsight, one is bound to wonder what influenced ministers and officials. Clearly the idea of international standards as means of entry to world markets appealed, but one wonders whether this was important for defensive reasons. The cynic might say it was important for control of those markets, and the evidence would bear him out. No doubt Government ministers were aware of the “Japanese miracle” (see below) and it is conceivable that they believed this quality management standard would deliver the same.

The British Government sought to “*enhance the status of standards as an instrument of improving efficiency and the international competitiveness of British firms*” by ensuring four things:

1. *Closer co-operation between the Government and BSI to develop British Standards which are of the required quality, command respect in world markets and are suitable for regulatory purposes and/or for public purchasing;*
2. *Commitment from the Government to make greater use of standards where appropriate in its regulatory functions and to explore new ways of recognising standards;*
3. *A much greater emphasis in public purchasing on linking requirements to existing standards rather than technical specifications particular to the purchasers;*
4. *The encouragement of certification schemes*

In doing this, the British Government set up the market and primed the pump. This white paper also began the confusion of “quality assurance” with “quality improvement”. During the 1970s UK industrialists had visited Japan to learn about the “Japanese miracle” [\(6\)](#). While they began to copy some Japanese practices, for example quality circles and suggestion schemes, they failed to “see” what was behind these practices – a fundamentally different way of thinking about the design and management of work*. Unaware of this crucial distinction, the Department of Trade and Industry funded “road shows” on the benefits of BS 5750 registration and provided funding to encourage organisations to use consultants in its implementation.

The recommended method of implementation was (and is) as follows:

1. **Look at your current organisation to see how it compares with the requirements of the Standard.** The Standard would ask you to consider such things as whether you had a formal way to review your contracts with your customers; whether your methods of working were documented and whether your manuals and procedures were kept up-to-date.
2. **What corrective action is needed to conform to the Standard?** This is to ask “How should we close the gap?” What actions need to be taken to ensure we comply with the Standard?
3. **Prepare a programme of work.** It becomes important to establish by when all necessary actions can expect to be achieved. The focus of the work becomes achievement of the plan, in order to achieve registration.

[6 \(Return to text\)](#) The Japanese miracle was based on systems thinking rather than command and control thinking. We return to this distinction in chapter 5. The Vanguard Standards (published at www.systemsthinking.co.uk) are based on systems thinking.

4. Define, document and implement new management systems and procedures.

Documentation is always central to the plan, it is the means by which the inspectors can do *their* work.

5. Prepare a quality manual. This ties together all of the above. It is the starting-place for inspection.

6. Pre-assessment meeting. The chosen inspector will often get involved in a pre-assessment meeting to help the client establish their suitability for going forward to assessment and thus registration. The interpretation of the Standard's requirements for the particular circumstances is the focus for discussion.

7. Assessment. The inspector determines whether the organisation conforms to its documentation. 'Do you do as you say you do?'

8. Registration.

Consultants and assessors provided much of the interpretation and guidance on the Standard's requirements. A correspondent whose career spanned the introduction of quality standards talked of his experience of the early period of BS 5750:

"The greatest fear we all had was where the 'assessors' would come from. We knew in our hearts that it would be from the redundant Government inspectors and 'surplus' industry 'quality' managers. This has turned out to be the most disastrous part of the whole scheme. There are many ISO 9000 consultants I knew from their old industry days that frankly I wouldn't have around, and now I find them pontificating on how to run a business!"

The emergence of doubts about the value of the Standard and the quality of advice on offer resulted in managers shopping around for assessors, perhaps wanting to find the assessor that will do the least damage; perhaps trying to find an assessor who would add value. As long ago as the mid 1980s assessing organisations were hearing their customers express serious discontent with assessment and registration. These organisations responded by changing the role definition of their "visiting professionals" from "assessing" to "auditing". They argued that the latter suggested they were in the business of providing advice and guidance — it was driven by a recognition that they needed to create value for their customers.

Yet this was to cross a boundary; an assessor should not be an advisor for that would open the possibility of undue influence. The original role, that of inspection, was the reason for the Standard's origins. The assessor was just that, someone who could relieve the customer of the need to check on suppliers (it was assumed that checking could not be entrusted to the supplier). Now the role of the assessor began to be being blurred: the auditor became both poacher and gamekeeper. This of course could lead to advice being tailored to meet the needs of the paymaster. Does this shift of emphasis get us any closer to improving quality and competitive position, or does it run the risk of taking us further away? There is, quite naturally (because the system encourages it), evidence of abuse of the power of the auditor's role. For

example, one assessing organisation sets targets for assessors to sell “value-added” services. Inevitably this will lead to malpractice.

Extending the Standard’s reach

Despite the growing discontent amongst organisations that were using BS 5750, the BSI, with the backing of the UK Government, took the Standard to the international standards community. It was the British Government’s intention to have British standards earn respect in world markets. In 1987, BS 5750 became ISO 9000. It marked the end of a period of committee work organised by the International Organisation for Standardisation and reflected a decision to promulgate the Standard throughout the international business community. The International Organisation for Standardisation (ISO), based in Geneva, is a world-wide federation of national standards bodies whose role is to promote the development of standardisation and related activities to facilitate the international exchange of goods and services. ISO 9000 was adopted to facilitate world trade. The basis for this decision is difficult to imagine, as there was a dearth of evidence available regarding the contribution made to economic performance.

For a document to become a standard it needs to go through committee drafts; then as a “Draft International Standard” it is made available to anyone who has an interest. A final draft is prepared following representations and it is put before the membership for formal voting. A 75 per cent vote in favour is required for acceptance. In the first ballot of members, the Japanese would not support the adoption of ISO 9000 and the Germans only came around after much persuasion. However, the required 75 percent voting in favour was achieved. The die was cast. This standard – a standard concerning the way work is designed and managed – was now set to be promulgated around the world, despite the lack of evidence of its success and the obvious discontent amongst its users in the UK.

ISO 9000 — a way of managing for conformance

Quality assurance, according to the Standard, is a *way of managing* that prevents non-conformance and thus “assures quality”. This is what makes ISO 9000 different from other standards: *it is a management standard, not a product standard*. It goes beyond product standardisation: it is standardising not *what is made* but *how it is made*. To use standards to dictate and control how organisations work was to extend the role of standards to new territory. To take such a step we might have firstly established that any such requirements worked — that they resulted in ways of working which improved performance.

Yet the plausibility of this Standard, and the fact that those who had an interest in maintaining it were (and still are) leading opinion, prevented such enquiries. In simple terms the Standard asks managers to say what they do, do what they say and prove it to a third party.

ISO 9000 (1994) paragraph 1: “The requirements specified are aimed primarily at achieving customer satisfaction by preventing non-conformity at all stages from design through servicing.”

To put it another way, the Standard asserts that preventing non-conformance achieves customer satisfaction. But does it? Of course it matters to customers that a product works. But there is no guarantee that the Standard will ensure even that. Furthermore, customers take a total view of an organisation — how easy it is to do business with — in respect of all things of importance to each and every customer.

ISO 9000 requires managers to “*establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements*”. Loosely translated this is “say what you do”. Management is supposed to “*define and document its policy for quality . . . including its commitment to quality*”.

What management would not declare its commitment to quality? But would they know what it means? Would they argue (as they should) that quality management is a different and better way to do business, or would they believe that ISO 9000 will take care of quality? The Standard encourages managers to think of “quality” and “business as usual” as separate and distinct. It helps managers avoid the revelation that quality means a wholly different view of management. Instead, the organisation “*shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility*” [for ISO 9000]. At a practical level this means only one executive might decide he or she had better learn a thing or two about quality. However, would being responsible for ISO 9000 lead to learning about quality or simply enforcing the ISO 9000 regime in an organisation?

Key to the regime is auditing. The Standard requires organisations to conduct internal quality audits to “*verify whether quality activities comply with planned arrangements*”. This can be loosely translated as “do you do as you say?” and the purpose of the audit is to see that you do. It was not until the 1994 review that the words were changed to “*quality activities and related results*”. It was a Standard which was rooted in the philosophy of inspection: fifteen years after its initial promulgation the promoters sought to extend the focus to results. But results or improvements assessed by what means? Inspection. By the time the Standard was adopted world-wide, quality thinking had moved a long way from the philosophy of inspection. It is now understood, at least by a few, that quality is achieved through managing the organisation as a system and using measures which enable managers to improve flow and reduce variation (which we explore in chapters 5 and 7). The defenders argue that there is nothing stopping a company having ISO 9000 and implementing methods for managing flow and reducing variation, but where are such companies? Few of the companies we researched, formally and informally, knew anything about this thinking. The Standard does not talk about it; moreover, the Standard effectively discourages managers from learning about it by representing quality in a different way.

According to ISO 8402 (quality vocabulary), quality is:

“The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.”

Everything we have learned about ISO 9000 suggests that the people who created this definition were thinking about the things which need to be controlled, those things which “bear on its ability . . .”. The builders of the Standard assumed that customer needs would be listed in contractual agreements between the supplier and customer. ISO 9000 has a “make” logic — procedures for “how you do what you do” — and a “control” logic — check to see that it is done. It is a relic of the era when contractual agreements were perceived to be an important device for regulating the behaviour of suppliers. In these ways, ISO 9000 encouraged “planning for quality”.

Planning for quality sounds plausible, but it assumes many things: that the plan is the right plan, that it is feasible, that people will “do it”, that performance will improve. It is an approach which, paradoxically, leads to poor decisions. Planners of quality systems, guided by ISO 9000, start with a view of how the world should be as framed by the Standard. Understanding how an organisation is working, rather than how someone thinks it should, is a far better place from which to start change of any kind.

Coercion resulted in growth

“You comply or we won’t buy” has been the modus operandi for ISO 9000. In the UK, Government led the market by placing this obligation on all suppliers of Government, whether national or local. It resulted in some famous cases. For example Morris Men (country dancers) had to be registered in order to supply (dance for) a local authority. However, such humorous examples only provided respite from and ridicule of the more general sense of obligation and drudgery.

The growth of ISO 9000 registrations was monitored by the Mobil organisation until 1998 when this work was taken over by the International Standards Organisation. In 1998 the most recent of these surveys was published – there have been no published data since.

The number of registrations to ISO 9000 in the UK shows a slowing of growth:

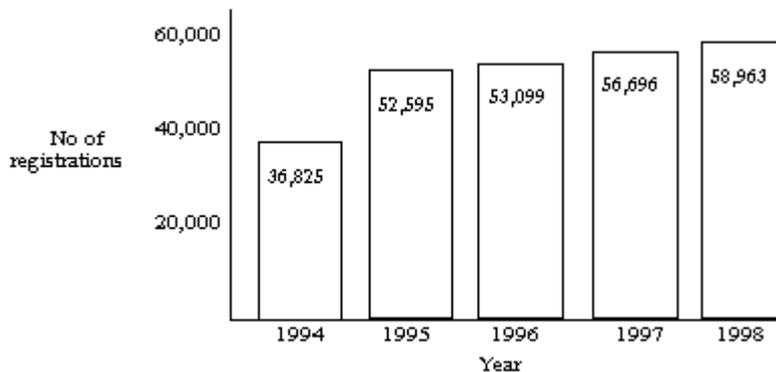


Figure 1.1 ISO 9000 registrations in the UK

The number of registrations in non-UK countries shows continued growth:

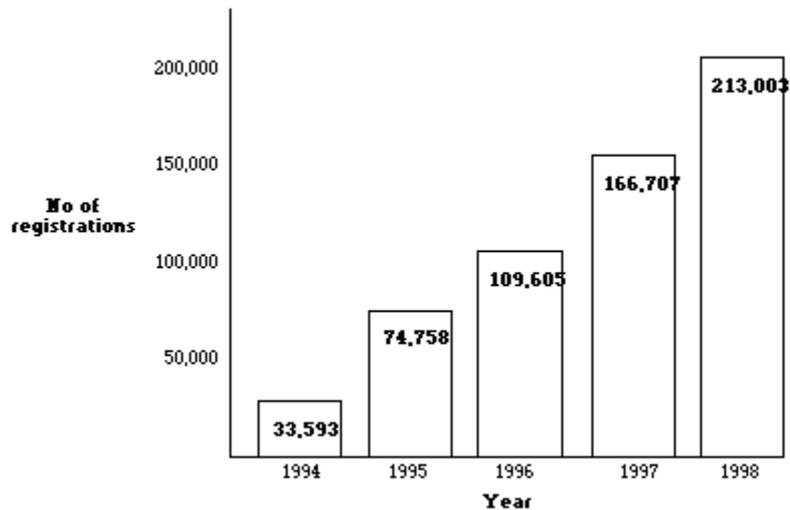


Figure 1.2 ISO 9000 registrations in non-UK countries

The number of countries using ISO 9000 has grown from 60 in 1994 to 143 in 1998. For the first time, the 1998 survey included information about ISO 9000 certificates being withdrawn. The main reason for withdrawal has been organisations deciding to discontinue registration to ISO 9000. The leaders are the UK and Australia. In Australia almost ten percent of registered companies have discontinued registration. To de-register is to swim against the tide of obligation. We know many senior players in the UK quality industry who want to de-register their companies but will not, for fear that it will be seen as not being concerned for quality.

Where did we go wrong?

New technologies brought new and serious problems. Our response was to control rather than understand. The leaders of the control school led opinion and Government followed. Government set up the machinery for promulgation and market-place coercion ensured growth. It is ironic that at the time our bomb factories were being controlled, some American bomb factories were being improved. This work was led by W. Edwards Deming, one of the figures who was to have a profound impact on Japanese manufacturing's quality and productivity. The methods employed integrated management with work, the essential solution sought by Admiral Rickover and they were the secrets behind the Japanese miracle.

The Japanese, Deming and others had a completely different conception of quality - it was concerned with methods for improvement, not control and conformance. We explore these methods and compare them with the methods promoted by ISO 9000 in chapters 5 and 7. First we turn to the research on ISO 9000's contribution to economic performance.

This is chapter 1 from “The case against ISO 9000”, second edition, published by Oak Tree Press, November 2000. ISBN 1-86076-173-9. The second edition includes a critique of the year 2000 revision and guidance on how to take a systems approach to interpretation and use of ISO 9000.

[1 \(Return to text\)](#) During one of many discussions of our views on ISO 9000, we met a man who had actually worked in a munitions factory during the War. He agreed that procedural control had solved the presenting problem. However, he informed us that other features of the factories were equally hazardous, yet they were not controlled because they were beyond the scope of the requirements! It illustrates a general problem with the control philosophy: people only pay attention to that which is controlled.

[2 \(Return to text\)](#) “The Never-Ending Challenge” a speech to the 44th annual National Metal Congress.

[3 \(Return to text\)](#) Report on Quality and Reliability Year, British Productivity Council, in association with the National Council for Quality and Reliability, 1967

[4 \(Return to text\)](#) British management has been characterised by Geert Hofstede (*Culture's Consequences: International Differences in Work-Related Values*, Sage, 1980) as having a “village market mentality” preferring serendipity and opportunity as the guiding traditions, choosing order only when it has clear benefits. Hence British management's rejection of the European directives on worker participation during the early 1980s and, more recently, their antipathy towards what they see as the strictures of the Social Chapter. There is little doubt that with respect to ISO 9000, British managers had no choice, they were coerced into registration

[5 \(Return to text\)](#) HMSO July 1982