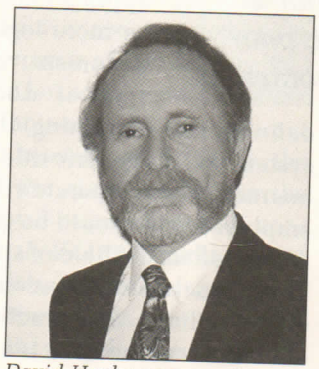
Let's Break The Mould

Has the traditional quality manual outlived its usefulness? David Hoyle parallels opposing views of the traditional ISO 9000-based quality manual with 20 sections against a manual which reflects how business is conducted, of a manual aimed primarily at ISO 9000 auditors against one aimed at employees, and of one written to respond to clauses in a standard against one written to govern the processes which run the business. He suggests that current ISO 9000-based quality manuals be scrapped and replaced with a more practical manual that adds value to the organisation.



David Hoyle: encouraging a move towards better quality manuals

Companies, particularly in the engineering sector, have been using quality manuals since the early 1970s as a vehicle for presenting their intentions regarding quality to their customers. They were mainly used in the defence industry as the company's response to Def Stan 05-21 or AQAP-1, the NATO quality control requirements for industry. Prior to this time documented practices were contained in department manuals with a few company manuals of procedures which applied to non-technical aspects such as administration, personnel and finance. The launch of ISO 9000 quality system certification in the 1980s led to a growth in the number of companies using quality manuals, although the standard at that time did not in fact require a quality manual to be produced.

The practice in regulated industries had been to document company practices in a hierarchy of departmental documents and to call the top-level document the quality manual. This indicated that it addressed the subject of quality rather than finance, personnel or engineering and was company-wide rather than related to any particular department. The manual brought together all practices within the company that directly or indirectly affected the quality of products and services provided to customers. Since finance, personnel, marketing, legal, catering and other support functions did not affect product or service quality their practices were not included. As a result, the nonregulated industries followed suit and called their top-level document the quality manual.

Initially these manuals addressed only those parts of the business where the practices were subject to contractual requirements. So, for example, a company engaged in military and civil work would have had a quality manual for its military work and nothing for the civil work. However, with the advent of ISO 9000 quality manuals started to cover all products and services supplied to customers regardless of customer requirements. They were, however, confined to the result-producing processes of the business and limited to describing those processes of the business for which there were requirements in ISO

9000. As with military contracts for which the manuals only addressed the processes needed to meet AQAP-1, AQAP-2 or AQAP-4, the ISO 9000 quality manuals only addressed the processes needed to meet ISO 9001, ISO 9002 or ISO 9003. So although the finance function, for example, was involved in all contracts for invoicing and cost accounting, their practices were not included in the quality manual.

The mould established in the early 1970s continued to be used into the 1990s. These manuals did not go beyond addressing the elements of these standards and many, even today, do not even describe the business since the standard does not in fact require them to do so. One of the reasons for limiting the manuals to respond to the requirements of the governing standards is that the more you say you do the more you are committed to doing. The less you are committed to the easier it is to demonstrate you do what you say you do. So the lesson many learnt was only document what you have to document to meet customer requirements. This has led to the perception that the purpose of quality manuals is to impress customers and auditors and not to benefit the business. After all, would we have a quality manual if we did not have to satisfy ISO 9000?

The 1994 version of ISO 9001 now requires quality manuals but is brief in what they are required to contain. Unfortunately, the associated guidance document ISO 10013 has reinforced the perception that their only use is to meet ISO 9000 by recommending that they be structured around the elements of ISO 9001.

Purpose Of Quality Manuals

The purpose of the quality manual is stated in ISO 9004-1 as: 'to define the outline structure of the quality system whilst serving as a permanent reference in the implementation and maintenance of that system'. Manuals should be documents that are used to perform work, otherwise why call them manuals: manuals which only outline things are not manuals.

The standard dealing with quality terminology, ISO 8402, does not state the purpose of the quality manual. It only states that it is a document stating the quality policy and describing the quality system of an organisation and that a quality manual *may* relate to the totality of an organisation's activities or only to a part of it. What a quality manual *shall* relate to is not stated. It adds that the title and scope of the manual reflects the field of application. Yet we still call these manuals quality manuals regardless of the field of application. As such the ISO 8402 and ISO 9004-1 definitions are therefore inadequate.

Descriptive documents are not manuals. For example, brochures and proposals are *descriptive* documents whilst manuals are *instructive* documents. In principle the quality manual contains the documented policies and practices of an organisation which serve the achievement of quality. Why ISO 8402, ISO 9001 and ISO 9004-1 provides the option for these manuals to include or reference the quality system procedures is unclear when in ISO 8402 it allows the title and scope to reflect the field of application. It would be more logical if the document, or collection of documents, defining (not describing) the quality system had the generic title of quality manual. Where separate volumes are employed these could be given titles which reflect the field of application. The manual should be a compendium of the policies and practices. More often than not though it is a repetition

A misguided belief that small is beautiful has led to a downsizing of quality manuals to little more than 30 pages. Size is not a deterrent, poor quality of content is

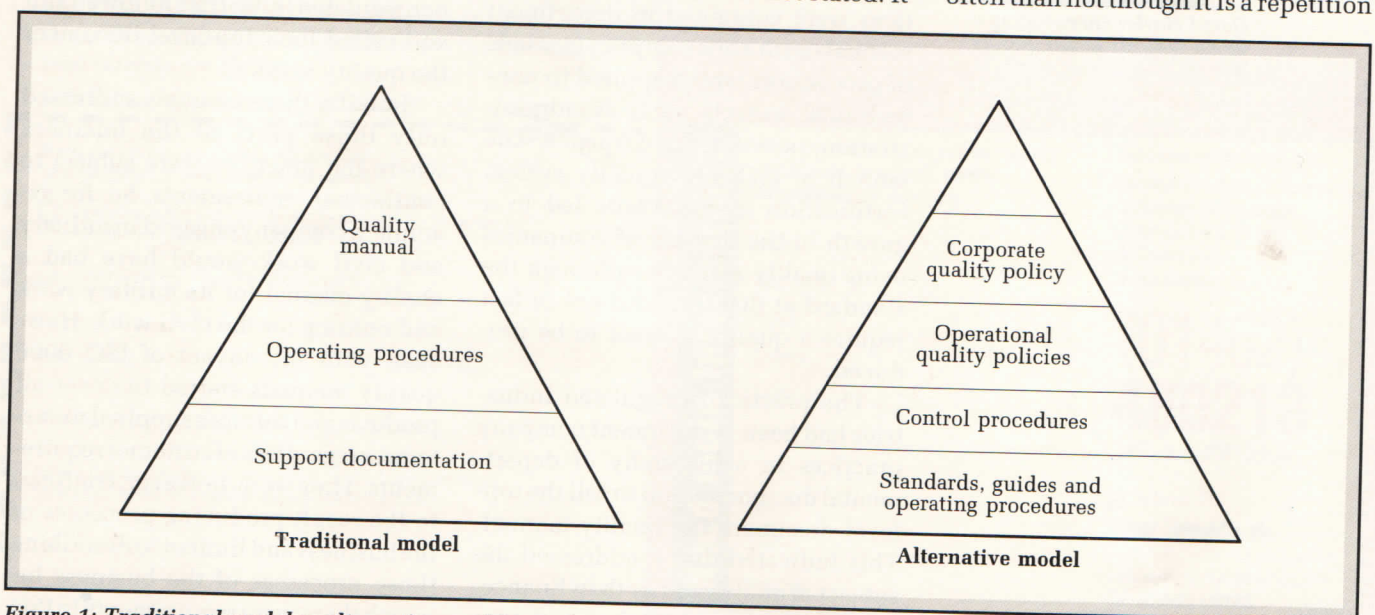


Figure 1: Traditional model v. alternative model

of the requirements of ISO 9000.

The manual is often shown as the top-level document containing only the policies but if the term manual was used correctly it should convey the impression that it contains both policies and practices. This difference is illustrated in Figure 1 where the traditional three-level structure shows the quality manual at the top of the pyramid and the support documentation at the bottom. In this model the quality manual, in reality, only contains the quality policies even though its title conveys a document of far more depth. In the alternative model there is no quality manual as such since the whole of the hierarchy is the manual, one or more volumes divided into parts each with a defined scope but all having the same function, that of defining the company's policies and practices for achieving quality.

If the quality manual were to describe the quality system fully, then a manual which merely responded to the requirements of ISO 9001 or ISO 9002 would be inadequate. However, there are thousands of manuals out there that merely respond to the clauses of the standard but as the requirement is vague they will continue to satisfy ISO 9000 auditors. But do they satisfy internal users?

What is the use of a manual which addresses the requirements of ISO 9000 when in practice employees do not work to ISO 9000 but to specifications and procedures? Why should company employees strive to satisfy auditors when they should be serving the business? A plausible explanation for maintaining a document which is limited in responding to the requirements of ISO 9000 is that it would be valuable in tendering for contracts and for use in quality system audits, but then it would not be a manual but an exposition. We could easily retain such a document in the hierarchy, but only if we inserted a more practical document between it and the procedures manual; one which defines how the business operates and lays down the operating policies. Shown in the alternative model, the manual containing the operational policies fulfils this role and acts as the link between the policies and the procedures.

Topic-based Documentation

ISO 9000 is a standard which specifies requirements under a number of headings. The rationale for the headings is that each of the topics has a bearing on the achievement of product quality. The order in which the requirements are stated is unimportant but several do follow the life cycle of a contract. However, they do not reflect a complete life cycle since marketing and disposal are notably absent from the elements of ISO 9001. The requirements address the factors which affect quality, obviously written from a hardware engineering viewpoint. The traditional approach in responding to these requirements has been to lay out the quality manual around the 20 elements of the standard and address each element if it is pertinent to the business. This has led to some considerable uniformity of quality manuals despite the fact that the introduction to ISO 9001 states that it is not the purpose of these international standards to enforce uniformity of quality systems. Some merely reiterate the clauses of the standard, others do go further and add explanation, but for many the requirements of the standard are turned into policies of the company. Very few actually state their strategy for meeting the requirements of the standard except by quoting procedures.

A misguided belief that small is beautiful has led to a downsizing of quality manuals to little more than 30 pages. People say that if it is any larger it will not be read. Regardless of the size they will not be read if they do not contain anything of use. Size is not a deterrent, poor quality of content is.

Upon questioning people as to how many requirements they think are in ISO 9001, the most common answer is 20. Many people are unaware that the number of 'shall' statements is as high as 138

A very common approach is to present policies which summarise the requirements of the standard rather than responding to all 300 or so requirements. It is interesting to note that upon questioning people as to how many requirements they think are in ISO 9001, the most common answer is 20. Many people are unaware that the number of 'shall' statements is as high as 138, and that within each 'shall' statement these can be broken down into several separate requirements. Most manuals do not address the 138 'shall' statements and many management representatives would argue that as ISO 9001 contains both high and low-level requirements, the more detailed requirements are addressed in the operating procedures or work instructions, and yet ISO 9001: 1994 requires quality manuals to cover the requirements of the standard.

In addition to reiterating the requirements of ISO 9001, whether or not expanded with some detail describing operational policies, it has become a common practice to list the related procedures at the end of the text before leading onto a new heading. Whilst somewhat more effective than simply including a list of related procedures in an appendix, related procedures are not necessarily implementing procedures. Often there is no direct relationship between the content of the policy and the related procedure either part of the policy is not addressed in the procedure or the procedure includes additional policies. It is as though one person wrote the policy quite independent of the person who wrote the procedure. Procedures should implement policies so there should be a direct correlation. Some polices apply to several procedures and yet the manuals hardly ever show this correlation. If we were designing software we would need to show traceability between the require-

ment and the means of implementation. It becomes a laborious task to verify that all the policies are planned to be implemented without a cross reference and even more difficult to maintain such a system, errors being detected by chance rather than by design.

The headings of ISO 9001 do not in many cases reflect the way in which work is carried out in the business. While some of the headings do relate, such as design, purchasing and manufacturing, headings on inspection and test, customer supplied product, inspection and test status, control of nonconforming product, inspection, measuring and test equipment, etc., are sometimes so out of keeping with the functions of the business that they jar with managers and staff. So much so that they regard the manual as for auditors' eyes only. So a quality manual laid out around the headings of the standard tends to be topic-based rather than process-based.

'A quality system should be the integration of interconnected business processes which collectively cause the supply of conforming product/service and prevent the supply of nonconforming product/service'

Another consequence of topic-based quality manuals is topic-based procedures: procedures which only cover the requirements of the standard and not the activities of the business. Some procedures respond to the concept of 'document what you do and do what you document' (DWYD²). This is another misguided belief as ISO 9001 does not in fact require this. What it does require is that the supplier establish and maintain a documented quality system.

Some procedures respond to the concept of 'document what you do and do what you document'. This is another misguided belief as ISO 9001 does not in fact require this

The DWYD² approach has also resulted in the development of departmental procedure manuals which, whilst going far beyond what ISO 9000 requires, do not in fact document a system but a collection of working practices which may or may not reflect a coherent system. Departmental procedures perpetuate departmental rather than corporate thinking, causing duplication, conflict, overlap and gaps in procedures. They also cause optimisation of departmental practices rather than corporate practices and permit fragmentation rather than encouraging harmonisation.

ISO 9000-based quality system documentation encourages ISO 9000-based auditing, i.e. audits performed by verifying conformance to ISO 9000 element by element. With this approach the audit plan presents the audit as a sequence of audits which follow the elements of the standard rather than the business processes. But how effective can an audit be which proceeds through the standard element by element since no elements apply to only one department. Even with element 4.4 on design control, auditors need to investigate conformance to 4.1, 4.5, 4.18, etc., as well as 4.4 to verify that design processes are under adequate control.

What is wrong with having a manual which responds to ISO 9000 as its only purpose? Well, it is not uncommon for companies to provide a specific response to their customer requirements because they know that is what they will expect. Should they respond with something different they may not be compliant, so may loose the contract to their competitor. A symptom of this approach is the inclusion in quality manuals of virtually blank pages with little more that a heading from ISO 9001 and a statement that this section is not applicable. This is a waste of space. It only confirms that the purpose of the manual is to demonstrate compliance with the standard rather than to define the policies and practices of the organisation.

To meet some customer requirements companies have to present an exposition of their operations. This is of no use other than as a declaration of commitment. It is not a working document within the business and acts only as a means of communication between the business and its customers. Is that what a quality manual is supposed to be or should it be, as the term implies, a document to be used to ensure the supply of quality products and services? If the document were to serve only the purpose of an exposition, then attaching the label 'manual' is inappropriate to say the least.

Process-based Documentation

Quality systems should be designed, not constructed out of in-stock components. Effective systems are designed to fulfil a specific series of functions and new components designed or selected to deliver the right performance. Constructing a quality system by documenting what you do merely formalises current practice, it does not create anything new. If there is no existing system but a random collection of activities which by chance cause products to meet customer requirements, then documenting such activities merely formalises them. It does not create a system. It only provides a system which delivers current performance. A system is an ordered set of ideas, principles and theories or a chain of operations that produces specific results and which work together in a regular relationship, therefore: 'A quality system should be the integration of interconnected business processes which collectively cause the supply of conforming product/service and prevent the supply of nonconforming product/service.'

Merely preventing nonconformity is not enough. A system which appears to prevent nonconformity may not cause conformity as some activities

may occur by chance or be informal but actually prevent nonconformity. Quality systems should enable an organisation to achieve defined objectives. If objectives are achieved but not through the quality system then the system is ineffective. A system that does not cause conformity is therefore a system which cannot be relied upon to achieve defined objectives.

Quality systems should enable an organisation to achieve defined objectives. If objectives are achieved but not through the quality system then the system is ineffective

The above definition of a quality system is more useful than that given in ISO 8402 as it indicates how it must function rather than what it consists of. It is because of this concept that quality systems should be designed around the business rather than ISO 9000. ISO 9000 reflects an imperfect model of quality assurance. It is a series of minimum requirements which all serve to prevent nonconformity and is therefore a constraint on the business but it is not a model of the business.

For the quality system to be of added value to a company, it should reflect how the company operates from receipt of customer enquiry through to fully satisfying customer needs and expectations. All work is executed through a series of processes which convert inputs into outputs of added value, so where else should one start but with a model of the business and how it operates. It amazes me that having looked at hundreds of quality manuals, few actually describe how the company operates. There are seldom any flow diagrams showing how business inputs are converted into business outputs but when designing any system, as any professional engineer will confirm, system design is usually depicted as a diagram showing how the inputs are converted into outputs. It is not a family tree of the people who designed it, or a list of the components which are used in the design (analogous with a procedures list). The procedures list is not a system design but a procedures list, no more than that.

A properly designed quality system should therefore have a system model showing the key processes and how they are connected. This should be supported by a hierarchy of flowcharts for each process indicating inputs and outputs down to a level where procedures can be identified. In this way every action has a purpose and is linked to other actions. Every connection represents a pathway along which products and information pass. Every policy is linked to a process and through to a procedure. Every document has a requirement which serves a purpose in the control of the processes. By designing processes with the aim of causing conformity and preventing nonconformity and hence providing controlled conditions, all the inputs, actions, verifications and outputs will be designed in. All the required documentation, records, material, equipment, personnel, etc., will be specified. By carrying out failure modes analysis and designing or redesigning the system accordingly, all the preventive measures needed will be built in. In other words, all the things will be put in place to cause conformance and prevent nonconformance.

For system engineers, quality system design should be familiar ground. Where we appear to have gone wrong is to ignore or forget our education and training and follow like sheep those who did not have system engineering skills, and construct our quality systems based on topics. Will environmental management systems go down the same road I wonder?

The Solution

What is described here is a situation that has evolved over a long time and in some respects has brought ISO 9000 into disrepute. Other than quality managers, many managers look upon the quality manual as something to satisfy the auditors but do not take seriously its use as a definitive statement governing their operations. The departmental procedures which they themselves have approved are considered of more importance. To convert a quality manual from a topic-based document into a process-based document requires a commitment to integrate the operations of the business and change the way the system is defined. It may or may not require a change to the way people work, but by moving away from a concentration on ISO 9000 to a concentration on the business processes, the system becomes of greater benefit to the organisation, facilitates improvement, reengineering and, when the time is right, facilitates enhancement towards a fully integrated management system. Those who change now will be in a good position to shoulder environmental, health, safety and financial management system requirements when and if they become market drivers. Furthermore, ISO 9000 will be changing within the next five years towards a process-based philosophy.

Biography

David Hoyle has over 24 years experience in quality management commencing with British Aerospace in spacecraft development and missile production and then as a quality manager with Ferranti International in computer systems development. Prior to becoming a freelance consultant he was with Neville-Clarke Ltd and continues to deliver its lead auditor and quality management training courses throughout the world. He has worked with both small and large organisations in product development, manufacturing and service sectors, conducting training courses and developing and auditing quality systems. Mr Hoyle's *ISO 9000 Quality Systems Handbook* was published in 1993 by Butterworth and has been translated into Spanish. It is now in its second edition (see book review on page 720). He is a Chartered Engineer, a member of the Royal Aeronautical Society and a fellow of the Institute of Quality Assurance.