Quality Systems - a new perspective

by

David Hoyle

(This article first appeared in **QUALITY WORLD**, *October 1996, and is reproduced here with kind permission of the Editor and Author)*

Across the world organisations are implementing ISO 9000 element-based quality systems. David Hoyle argues that a new perspective must be adopted to focus on an organisation's processes and to move away from this rigid interpretation. He looks at what a quality system comprises and, taking each component in turn, reviews the substance of quality management

Around the world there are many types of quality systems but one dominates the field: the ISO 9000 element-based quality system. Where it originated is uncertain but it is advocated with monotonous regularity. This approach facilitates the comparison of various systems, but it defeats the objective of providing systems that enable organisations to design, develop, produce and deliver products and services that meet customer needs and expectations. Quality systems should be developed to serve the needs of the business not the auditors.

Off-the-shelf packages should be outlawed even though they can save money in the short term. While any reduction in costs is to be welcomed, these solutions are akin to the student who studies past exam papers and learns how to answer certain types of questions, then gets stuck when faced with a question that appears for the first time. Such solutions remove the opportunity for people to learn. They may be able to pass the assessment but they are not educated.

Using software tools will help maintain control of documents and speed development, they will also often provide useful aids to data collection, analysis, retrieval and storage. However, many of the packages have built-in prescriptions and templates for documentation which may not suit your organisation and will force you into the ISO element approach.

Every organisation wants a painless and swift solution to meeting ISO 9000, but in doing so they are missing the point. ISO 9000 is not about a system of documentation; it is about quality systems. ISO 8402 defines a quality system as the organisation structure, processes, procedures and resources needed to implement quality management.

Organisational structure

To many this means an organisation chart or several charts that depict the various positions and their relationships, but the organisation structure is far more than a piece of paper with boxes containing names. As David Packard[1] remarks: 'The way the organisation is structured affects individual motivation and performance.' Well, if the structure is merely a chart, it is more than likely to demotivate rather than motivate by showing how low some people are in the hierarchy. So what else reflects the organisation structure?

Consider two organisation charts, one for a private company and another for a unit of the military, both of which maintain road vehicles. They may well look alike on paper, but in practice they are quite different. The private company may operate in a way that provides employees the freedom to innovate, to participate in decisions, to discuss matters directly with the managing director, and to work flexible hours. The military unit has none of these freedoms. Every employee has to obey the instructions handed down from above without question. Each operation is

appropriate to its environment but neither is shown on the chart.

If the quality system is to comprise the organisation structure then it must consist of more than a chart. There should be a description of the organisational policies which are employed to foster individual motivation and performance. These could cover:

- division of work within the organisation and its component parts
- selection of personnel for appointments and the promotion policies
- defining and communicating responsibility and authority
- staff involvement in policy decisions
- the way policies and instructions are issued and feedback obtained
- the use that is made of staff suggestions
- resourcing of projects and redeployment of surplus resources
- employee benefits, share options, sick pay, insurance schemes, etc.
- how managers obtain the confidence of the workforce
- how managers show their trust in the workforce
- policies on working hours, holidays, absence, etc.

The vision and values to which the organisation subscribes will also be important and the ways in which these are embedded in the culture and periodically reinforced. What all this relates to is, of course, the style of management. Therefore, the organisation structure is a reflection of management style. To reflect this accurately, the description of the organisation structure in the quality manual should cover all significant facets of the management style such as those above. Many claim that ISO 9000 says nothing about the people aspects of quality and, since the achievement of quality is primarily dependent on people, this is a serious omission. However, by taking a new perspective towards the meaning of an organisation structure, all manner of human factors can be introduced into the system.

The typical response to clause 4.1.2.1 of ISO 9001 is to insert an organisation chart and a few job descriptions in the quality manual. This hardly reflects an organisation structure of the type described above. The manual should reflect the policies of the organisation towards the other elements of the standard, so why when it comes to clause 4.1.2.1 are no policies ever stated? Only a picture of the organisation as it is currently formed is portrayed - no policies for shaping the organisation to cope with the varying demands of its customers or for responding to change.

Processes

Processes are the means to transform inputs into outputs of added value. They include all the materials, machines, environment, personnel, documentation and techniques to convert given inputs into required outputs. And yet the majority of quality manuals do not describe the processes of the organisation. All they describe is the organisation's response to the elements of ISO 9001 or ISO 9002 which themselves are not in general processes but topics. If the manual is supposed to describe the quality system, then one would expect it to describe the processes of the business. A manual laid out in ISO element fashion is not describing a system, it is merely responding to the requirements.

Take an engineering example. A requirement specification for a product will detail the features and characteristics which a product needs to exhibit for it to fulfil a given need, such as performance, reliability, safety, physical and functional requirements. These requirements do not describe any particular product since there could be many solutions all differing significantly in form, construction and technology. Thus a supplier's description will be unique. It will illustrate the product with diagrams and pictures, and the actual performance characteristics will often exceed those in the original requirement specification. The product does not have a size function, a reliability function, a safety function, etc. It consists of a carefully chosen set of components which are interconnected to provide the stated functions reliably and safely, etc. Even when considering the operational functions, it is not often possible to point to any component and claim that it alone fulfils a requirement of the specification. Collectively they work together to deliver the required performance. So why when describing quality systems are the requirements simply repeated?

To meet the intent of ISO 9001 and ISO 8402, processes such as system management, marketing, design, development, purchasing, manufacture,

shipping, distribution, installation and servicing, need to be described and shown to meet the relevant requirements of the standard. In other words, lay out the manual as a series of processes, not as elements. Turning again to the people factor (which many say is absent in ISO 9000), processes involve people. People contribute both tangible and intangible inputs, such as leadership, to the process. Without leadership the processes will not function effectively.

Procedures

This is another term that has been abused by consultants and auditors. Procedures seem to have become the documents which relate to an element of ISO 9001 or ISO 9002, such as contract review procedures, inspection and test status procedures, and corrective and preventive action procedures, even responsibility and authority procedures. Procedures seem to be limited to these elements while all lower level procedures are called work instructions. Where did this concept come from?

The ISO 8402 definition has its drawbacks but it does not imply any levels. A procedure is simply a way of proceeding to accomplish a task. It can be a few lines or a book full of instructions. How do we proceed to do anything? Step-by-step rather than in huge jumps. One might eat an elephant a bite at a time, so they say - this then is the procedure; but you may need to preface the eating with a few preparatory steps to avoid indigestion! Any document that lays out a way of doing something step-by-step is a procedure. There is no reason why the word in ISO 9000 quality systems should be limited to documentation levels below the quality manual.

ISO 9001 requires procedures to be established, documented and maintained for 18 topics, although this does not mean 18 documents are required. The word 'procedure' in the standard is always plural, thereby implying many procedures may implement a particular requirement.

To illustrate this point take corrective and preventive action procedures as an example. In several systems, these two quite different topics are covered in one procedure usually with the result that the company is non-compliant with the preventive action requirements but still gets registered. Many people are confused by the meaning of corrective action, and treat it as the action to fix the nonconformity. Indeed clause 4.14.2 of the standard addresses customer complaints under corrective action and the complaint must be fixed to prevent it from recurring. However, three actions need to be taken and all require different procedures: remedial action, corrective action and preventive action. The first two are related and may follow in sequence, but preventive action cannot be taken on a problem that already exists. From the definitions in ISO 8402, corrective action is action taken to prevent the recurrence of a nonconformity, and preventive action is action taken to prevent the occurrence of a nonconformity.

Corrective and preventive action procedures cannot be mixed together. In fact many actions, such as planning, training, failure modes and effects analysis, auditing, and management review, are preventive actions but do not come under the preventive action heading. They are often the subject of other procedures.

Resources

The system includes the resources to implement quality management. This is sometimes interpreted as being limited to the numbers of inspectors and auditors employed and the organisation concerned is duly registered, Resources include personnel, materials, equipment, facilities, plant, space, finance and time. To describe resources the system would have to describe how each requirement is identified and acquired. Few, if any, manuals go this far. But again, resources is a topic and so there cannot be a single procedure to govern its identification and acquisition.

A system without adequate resources will not function. If the managers do not allow sufficient time for the procedures they have issued to be carried out, then the system is ineffective. If there are insufficient or inadequate tools, equipment, staff and space for the activities described by the procedures, then the system is ineffective. If the staff is not equipped with the education, training and motivation needed, then the system is not effective.

Resources from this perspective take on a new meaning, but how many auditors really assess the organisation's resources? Very few, primarily because there is no documentation required by the standard on which to judge conformity. However, while clause 4.1.2.2 may not require documentation, clause 4.2.1 requires the system to provide a means of ensuring the product conforms to specified requirements and this has to be documented. If the product is not meeting such requirements it could be that there are

inadequate resources. In clause 4.2.3 suppliers are required to consider the resources needed to achieve the required quality and in clause 4.3.1 suppliers are required to review contracts before acceptance to ensure that they have the capability of meeting the requirements. Again under clause 4.4.2, design staff have to be equipped with adequate resources and in clause 4.9 the supplier is required to use suitable production, installation and servicing equipment - all related to resources.

Clause 4.17 also requires internal audits to determine the effectiveness of the system, but no audit programme (to my knowledge) does this. Even third party auditors do not check for effectiveness and no standard in the ISO 9000 series suggests how this might be carried out.

A quality manual that describes the resources required to implement quality management should identify the plant, personnel and equipment at its disposal to execute its business. In the manual this need be no more than an outline supplemented by the policies that govern the identification, acquisition and disposal of resources with reference to the procedures in which these polices are implemented. It would also need to indicate how such data was made available to the decision makers, especially those accepting contracts.

Finally, returning to the people factor, motivation might be an element of resources and the organisation structure will affect individual motivation. Everyone has the ability to be motivated - the secret is to create the right environment to extract that drive.

Conclusions

Is all this required in ISO 9001? Yes. ISO 8402 is part of ISO 9001. It defines both a quality system and a quality manual. So the quality manual has to describe the quality system, not the requirements of the standard that are satisfied by the system. The words used in the ISO 9000 series must be respected for the standards to be of value.

The peddlers of the element approach have done ISO 9000 a great disservice. In Asia, where ISO 9000 is still attracting a big following, there is a danger that pundits from the West will eventually be thrown out when so-called quality systems do not deliver the predicted benefits. The systems may enable them to compete in Europe but a random collection of components that fail to function as a system will not improve their business. In the USA it is the same.

There are other more beneficial approaches to ISO 9000 than an element-based system. A new perspective must be adopted now to show total quality management advocates that ISO 9000 is not all about documentation without an ounce of the human element.

Author's note

This new approach to quality system development is the subject of a new book by David Hoyle which follows his *ISO 9000 Quality Systems Handbook, Quality Systems Assessment Handbook* and *QS 9000 Quality System Handbook.*

References

1. Packard, D, The HP Way, 1995, Harper Collins.

Biography

David Hoyle, CEng, MRAeS, FIQA, has over 25 years experience in quality management holding managerial positions in the aerospace and computer industries. As a management consultant and registered Lead Auditor firstly with an international consultancy practice and then as an independent, he has worked in product development, manufacturing and service sectors assisting both small and large companies throughout the world in developing and auditing quality systems and delivering training courses in quality management. He is a Director of the Institute of Quality Assurance and Chairs the Institute's Business Development Board and Publications Panel.

*****

"Praise does wonders for the sense of hearing."

- Bits and Pieces