

TRANSFER TO THE PROCESS

This critical examination of ISO 9001:2000 looks through the hype and sees a less than perfect standard. While applauding the emphasis on business processes, it argues that the language of the standard can be at times confusing and suggests alternative definitions for some of the clauses.

ISO 9001:2000 undoubtedly represents an improvement over previous incarnations of the standard. Unfortunately it can still be a difficult document for businesses to implement. Fundamental among the problems is the way in which the adoption of the process approach is promoted within the document, apparently without a clear understanding of this very approach.

It is apparent that even if the standard is a good guide against which to assess a QMS, it is not, critically, a document around which to build one. The following observations will help interpret some of the more difficult language contained in ISO 9001:2000. They should also help understand how to adopt a process approach.

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Many organisations will waste a vast amount of time trying to implement ISO9001:2000 without the required understanding and knowledge of the concept of a "business process". Most managers find it difficult even to recognise their key processes, far less to define them as part of a structured management system. "Processes" have not replaced "procedures" - processes have always existed because that is how day-to-day business operates. What has changed is the focus on the flow of work through and amongst departments rather than on what happens within a department.

A process-based management system should be a simple description of what the organisation does. Process descriptions can then be reviewed in relation to the requirements of external standards, legislation and policies and refined if necessary. The involvement of people, the use of reference documents and the impact of resources and influences will be integrated into the system in the most logical way. A good starting point for designing a system which meets the requirements of ISO 9001:2000 would be to recognise that the wording and structure of the standard itself are not the ideal place from which to start planning such a system.

PROCESS (OUT OF) CONTROL

By analysing quotes from ISO9001:2000 it is possible to see why companies are struggling to get to grips with the process approach. At several points the text in the introduction is inaccurate. First businesses are encouraged: *'to enhance customer satisfaction by meeting customer requirements.'* The phrase *'to enhance'* is misleading. To enhance satisfaction requires you *'to exceed'* customer requirements or perhaps to meet their expectations (if these go beyond basic or stated requirements). The words *'to ensure'* would be more accurate here.

Further down it is claimed that: *'An activity using resources...can be considered as a process'*. Unfortunately, in the companion standard ISO 9000:2000 (fundamentals and vocabulary), a process is defined as *'a set of interrelated or interacting activities...'*

Another claim in this section is that: *'The application of a system of processes within an organisation...can be referred to as the 'process approach.'* This is classically misleading. A system of processes is not *'applied'* within an organisation. The processes are already there. The process approach is about your view of what is already happening - as confirmed by the use of the word *'approach'*.

The text continues: *'together with the identification and interactions of these processes...'*. *'Identification'* is clearly necessary, but the processes are already interacting, even if management is not always enlightened enough to see it. The simple existence of these *'interactions'* has nothing to do with *'the process approach'*. Again it is the focus on what is already there that marks the change. Perhaps *'the identification and management of the processes within an organisation'* would be a more helpful way of wording this phrase.

The process approach does not in itself provide control of the interfaces (which is admittedly where many problems occur) - it just makes it easier to see what is going on. It is up to you to *'manage'* what you see.

Because of this, definition of the processes that need to comply with the standard would benefit from an initial "Assess" step for all but new-start companies (with due respect to Deming's PDCA cycle).

AUDACIOUS CLAIMS

One of the most audacious claims in ISO 9001:2000 is that: *'The model of a process based management system shown in figure 1 illustrates the process linkages presented in clauses 4-8.'* I have yet to find anyone who agrees with this claim. Rather, the illustration creates unnatural categories of processes, implies that *'management responsibility'* is a process and suggests that measurement is a distinct process rather than, as is often the case, being an intrinsic part of other processes.

The diagram called *'Model of a process-based QMS'*, like most diagrams in this style, fails to aid understanding. The figure shows a two-way information flow between customers and *'management responsibility'*. Nowhere *in section 4 (management responsibility)* is there any suggestion that top management communicates with customers. The only link shown from *'management responsibility'* is into *'resource management'*.

The requirements stated under '*management responsibility*' have an equal if not greater impact on '*product realisation*' and on '*measurement, analysis and improvement*'. It would make more sense if '*management responsibility*' was the label on the big circle in the background, with the top box labelled '*planning and organising*'.

For some reason '*customer requirements*' are described as a '*value-adding activity*', despite not being an activity at all, never mind one that adds value. The identification of a customer's requirements may be the input or trigger for the organisation to provide goods or services, but it is the production processes that add value.

Why are only two information flows shown, and why are these flows only to and from customers? As the standard correctly states elsewhere, internal communication is equally important.

SECTION 1

In *section 1.1 (scope - general)* again the phrase '*to enhance customer satisfaction*' appears. Another strange claim reads: '*NOTE: the term 'product' applies only to the product intended for or required by a customer.*' However, section 7.4.1 says that a product is also something that the organisation receives from a supplier. In section 3 (terms and definitions) the standard writers are at pains to draw a picture showing how the terms 'supplier' and 'customer' relate to the organisation. ISO 9000:2000 is supposed to define terms.

SECTION 4 (QMS) AND SECTION 5 (MANAGEMENT RESPONSIBILITY)

4.1 General requirements

'*The organisation shall d) ensure the availability of resources and information...*'. Information is a resource and if this is clearly understood it should not need to be stated separately.

4.2.2 Control of records

'*Records shall be established and maintained to provide evidence of conformity to requirements...*'. This raises the questions, conformity of what, and to which requirements? There are plenty of superfluous words elsewhere in the standard, but there are a few short here.

5.1 Management commitment

The implication of '*continual improvement*' is misleading. The dictionary definition is not that of ISO 9001:2000, which uses '*recurring*'. '*Ongoing*' fits the bill better. But it would be more sensible to expect '*a regular review and assessment of improvement opportunities, and the implementation of those which make business sense*'.

SECTION 6 - RESOURCE MANAGEMENT

Why does *section 6.1 (provision of resources)* repeat the wording from section 4.1 in a slightly modified format? The old style narrative quality manual invariably had sections which duplicated responsibilities and procedures already defined elsewhere, and here ISO 9001:2000 has done the same.

6.2 Human resources

Section 6.2.2 (competence, awareness and training) refers to: '*Performing work affecting product quality.*' It seems strange to introduce the term '*work*' at this late stage - whatever happened to '*activities and processes*'? The wording implies that '*work affecting product quality*' differs from the processes defined in the quality system.

'*Performing work*' could have been reworded as '*involved in the processes needed for the quality management system*' (as in 4.1). In fact, this requirement would be better located in 4.1 as it relates to managing processes.

SECTION 7 - PRODUCT REALISATION

Have you noticed that this term is not even defined in ISO9000:2000? Better still if it had not been used at all.

Planning of product realisation

This section states: '*The organisation shall plan and develop the processes needed for product realisation.*' Unless you are a start-up company, you will already have planned and developed the processes, because they are already in operation. It is rather late in the managing of a process for ISO 9001 to say this - '*define and manage*' would be a more sensible choice of words. And is this not what 'quality management' is all about? (Is this not what 'management' is all about?).

THE CRUX OF THE PROBLEM

An even greater concern is the explanation of a *'quality plan'* in *section 3.7.5, note 1* which talks of *'procedures...referring to quality management processes and to product realisation processes'*. Quality, like management, is not separated from doing things and making things. The process of delivering a service, or of making goods to order, must be managed to avoid damage to the environment, to develop your staff, and to produce an output that will satisfy your customer. It is dangerous to suggest that *'product realisation'* processes are somehow distinct from quality management processes. Yet the entire standard gives you that impression. There is a real argument for taking the 'quality' out of 'quality management'.

Customer-related processes

Why are these classified as a distinct set of processes? In many situations, they are 'merely' stages or tasks ('activities') within the routine processes involved in getting and doing work. Remember the old-style quality manual? Twenty 'procedures' whether you liked it or not - and all because ISO 9000:1994 had 20 sections.

Design and development

The confusion between goods and services (ie 'products') raises its head again. If you develop a service, such as a training course, and file the slides and course notes ready for the first presentation day, this is the same as making (producing) a widget and putting it in a box in stores. The design and development of a new product is a prior process to full-scale production - but what happens for a service? ISO 9001's manufacturing bias is not dead yet.

7.3.1 Design and development planning

'The organisation shall plan and control...'. All processes should be defined and managed. As is usually the case with narrative documents, there is a tendency for repetition. This section would be far easier to read if *'design and development'* was not mentioned nine times in ten lines. *'The organisation shall manage the interfaces between different groups involved...'*: why just for this process? The interfaces between departments are often one of the key areas of confusion within a process. One of the key benefits from managing processes comes from identifying the interfaces, clarifying how they should work and taking steps to ensure that they do.

Design and development inputs

'Inputs relating to product requirements shall be determined...'. I see no difference between this wording and section 7.2.1 (determination of requirements related to the product). Another key omission from ISO 9001:2000 is the concept of an 'objective' for a process - not *'quality objectives'*, but what the process is supposed to do or achieve.

7.5 Production and service provision

Would this not be more consistent and clearer if it was *'Production of goods and services'*?

7.6 Control of monitoring and measuring devices

'The organisation shall establish processes...'. Monitoring must, by definition, occur alongside the process being monitored. Measurement will often be the same. So *'the organisation shall establish suitable methods...'* might fit the bill better.

SECTION 8 - MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Here again the standard talks about separate processes for *'monitoring, measurement, analysis and improvement'* which, depending on the type of business, will not always exist. This is one of the most important elements of the new standard but it is misleading. If measures do not exist then they should be established and managed as integral to every process.

8.2.1 Customer satisfaction

This feature of the new standard has already been debated extensively in the media. Some organisations will find it very difficult to contact their customers after a sale, never mind get a useful comment from them. And there is also much debate about how reliable such comments are. Will external auditors have enough relevant knowledge in CRM to be able to decide what is reasonable in a particular case?

HOW TO MANAGE THE PROCESS OF COMPLIANCE

So what should you do? Put the standard aside until you understand 'processes' and have defined your key processes in a simple, structured system. For each process, identify its objective(s) and its trigger or input, and then define its tasks and the output(s). It is important to consider the required resources and controls and influences on how it works.

Formal and informal business processes have always existed because that is how day-to-day business operates. Nothing is achieved within an organisation that is not part of a process. Your processes already exist - all you need to do is to recognise and describe them.

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