ISO 9000 focus moves from compliance to achieving results

According to Matt Seaver, one of the problems with the 1987 and 1994 versions was that many organizations saw ISO 9000 as an end in itself. They contented themselves with developing procedures that complied with the 20 elements of the standard – and then wondered why their quality system was not producing much in the way of benefits.

The new process-based versions force the user to stand back for a view of the whole picture of the enterprise and how the standard can serve it. This article gets to the essentials of the ISO 9000:2000 series and advocates a results-oriented approach to implementation in which the standard is not the objective, but the tool to reach objectives.

There is no point denying that the ISO 9000 series of standards has received some severe criticism in the past. Most of it related to perceived weaknesses with regard to its ability to deliver real benefits and an over-emphasis on paperwork. I have always felt that this failure to deliver had more to do with the way in which quality systems were set up than any inherent weakness in the standards themselves.

However, in the true spirit of "customer focus", ISO technical committee ISO/TC 176, which is responsible for the ISO 9000 series, undertook an in-depth revision, having first carried out a worldwide survey of customer requirements, with a view to producing a standard appropriate to the start of the 21st century. The result is a set of standards that are very different from the ones we have grown to love or hate over the past 14 years.

Fundamental changes

There are several ways in which the new standards differ fundamentally from the old ones. I'll deal with just a few here. Firstly, our quality management initiatives should now be based on eight principles that encapsulate the essence of good quality management. These principles are:

- **Customer focus.** Overall success for the organization depends fundamentally on how well it satisfies its customers' expectations

- **Leadership.** Without leadership and a firm commitment to quality by top management all efforts are bound to fail. The senior managers define the atmosphere in the organization and this will determine the attitude of all other employees in the organization.

- **Involvement of people.** Without the co-operation of all persons involved there is little chance of objectives being met. People must be involved at all levels, and must feel that they have an interest in the success of the enterprise.

- **Process approach.** Any assignment or project is more effectively carried out if it is treated as a process rather than as individual, discrete tasks.

BY **MATT SEAVER**

Matt Seaver was actively involved in both the 1994 and 2000 revisions of the ISO 9000 series, as a participating expert in ISO/TC 176.

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As the author of this article is Irish, it seemed appropriate to illustrate the article with a couple of Irish successes in achieving ISO 9001:2000 certification.

Here, Edgar E. Vicanco, (left) President of the Ireland-based Speciality Testing Division of the US Group Beckman Coulter Inc., is presented with an ISO 9001:2000 certificate (from the National Standards Authority of Ireland – NSAI) by the Lord Mayor of Dublin, Councillor Michael Mulcahy.

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- **System approach to management.** The business of an organization can be managed more effectively if the various processes involved are controlled as part of an overall system. Managing the interrelation of the processes ensures that each process contributes to achieving the objectives of the organization.

- **Continuous improvement.** We should not be content to operate at the same level forever. Consistency is fine, but improvement is even better. Competitors are constantly improving. We need to improve also if we are to maintain or improve our position relative to them.

- **Factual approach to decision making.** Too often critical decisions are taken on the basis of intuition or emotion. It is much more effective to collect and analyze relevant data and facts, and to base the decision on this.

- **Mutually beneficial relationships with suppliers.** Quality and reliability can be greatly improved and significant financial benefits achieved by developing strong relationships with trusted suppliers on whom you can rely.

While all of this is totally commendable, there is nothing earth-shatteringly new there, and how many of us can honestly say that we have truly operated to those principles in the past, and not simply paid lip-service to them?

The second change in approach addresses one of the main criticisms of the first two editions of the standards, that is, that they did not seem to aim at results and genuine improvement of performance, but rather seemed to concentrate more on the formality of the system and compliance with the documented procedures.

The prominence that paperwork attained was never intended by the original authors of the standard. It was the observers, the fringe experts not involved in its development, who decided that "procedure" meant "documented procedure". The result was that many of us were forced to produce large manuals of highly detailed procedures, ignoring the fact that personnel may have been highly trained or closely supervised. Often these manuals contained large sections of material reproduced from other sources, such as equipment suppliers' manuals. A little thought would have shown us that many of these documents were of little value to us. But the experts said we had to have them.

Happily, that approach has now been discouraged in the new standard. In fact, there are only six instances where a documented procedure is prescribed:

- control of documents;
- control of records;
- internal audit;
- nonconformity;
- corrective action, and
- preventive action.

That is not to say that you do not need other procedures. It is extremely unlikely that an effective system could be built with just six written procedures. But the point is that each organization chooses which additional ones are appropriate in the circumstances.

Changing existing documentation

The first question that most people ask in relation to documentation is whether there is a need to change the quality manual and other quality documentation. The short answer is that some changes will be necessary. The guidelines issued by ISO/TC 176 state clearly that there is no requirement, as such, to change the documentation, but in practice the new regime would be difficult to manage without some changes.

The changes may arise in two areas, the quality manual itself, and those elements of the standard that are not already addressed in your existing system. Rearranging the existing quality manual to the new structure is, in theory, little more than a cut-and-paste exercise, but, in practice, it can be quite a complicated business, and requires a good knowledge of the new standard.

When that has been completed it will be apparent if there are gaps in the system. The extent of those gaps will depend on how comprehensive the existing system is. Additional *necessary* procedures resulting from new elements in the system should be written in the "new" manner, taking care not to include unnecessary detail or any material that is not useful.

Some organizations will have little, if any, action to take. Most of my clients whom I helped reach compliance with the old standard have little

to do, since I have always encouraged my clients, for example, to document their processes, to evaluate the effectiveness of training, and to measure the level of customer satisfaction, and to set up effective channels of communication, on the basis that these were useful activities, even though they were not strictly required. Many organizations, however, will have done the minimum necessary to achieve compliance rather than seeking to use the ISO 9000 system as a tool for achieving results.

It's results that matter, not the methods

ISO 9001 and ISO 9004 now place primary emphasis on results rather than the methods employed and mere compliance with documented procedures. The story is told about the training organization that undertook an updating of its trainer register. The new procedures for registration of trainers required that they produce copies of their trainer qualifications. Some of the older trainers on the register had lost the evidence of their training as trainers. The result was that they had to attend a training skills course in order to remain on the register! In this case, the means was mistaken for the end, and had become the end.

At the presentation of an ISO 9001:2000 certificate by the National Standards Authority of Ireland (NSAI) to the Irish company Professional Merchandising and Marketing Services (PMMS) were, from left:

Simon Kelly, CEO of NSAI; Eve MacSearraigh, of PMMS; Paula Lawlor, Managing Director of PMMS; Noel Treacy, Irish Minister for Science, Technology and Commerce, and Dan Tierney, Chairman of NSAI.

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The objective of the exercise was to ensure that all trainers on the register were competent and one factor, certainly, in evaluating the effectiveness of trainers is to check their trainer qualifications. However, this then became the "necessary and sufficient" condition for demonstrating competence, ignoring the fact that there are other ways to demonstrate trainer skills, and that a person who has successfully attended a training skills course may be utterly useless as a trainer.

Don't mistake the means for the end! Concentrate on the results, not the methodology. ISO 9000 is a tool to help you achieve an objective. It must not, itself, become the objective.

About the author

Matt Seaver has been an expert member of various working groups of ISO/TC 176 since 1992, and was actively involved in both the 1994 and 2000 revisions of the ISO 9000 series.

He has a PhD in biochemistry and for 13 years was quality manager in the baby food industry. For the past ten years, he has worked a quality consultant working, in particular, for clients in the food industry.

He is co-author of *ISA 2000; the system for occupational health and safety* and author of *Implementing ISO 9000:2000*, both published by Gower Publishing, Aldershot, United Kingdom.

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New structure

Another obvious change relates to the structure of the standards. The range of standards in the ISO 9000 family has been streamlined and now there are just two core operational standards, ISO 9001 and ISO 9004. ISO 9002 and ISO 9003 no longer exist. From now on, everybody works to a single requirements document, ISO 9001, and where a particular requirement is not applicable, this is recognized in the scope of the quality system certification.

In addition, ISO 9004 and ISO 9001 have been brought into closer alignment. In the past, users of the standards did not always understand the function of ISO 9004, often mistaking it for guidance on how to comply with ISO 9001, or implementing ISO 9001.

In fact, the very notion of "implementing ISO 9001" is false. ISO 9001 is merely a collection of tasks that must be carried out in any effective quality management system in order to assure product quality and customer satisfaction. The document that describes what a system should address, in the interest of all its stakeholders, is ISO 9004.
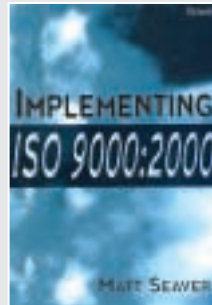
The paragraphs of these two standards are now almost identical, ISO 9004 indicating best practice, or guidance on what you should address in your quality management system for best business results, while ISO 9001 describes those specific activities that you must undertake regularly for reasons of customer satisfaction, or quality assurance.

Reading the new ISO 9004 standard, it should be very clear that it does not offer any guidance on how to comply with ISO 9001 requirements. Furthermore, ISO 9004 contains a number of initiatives that are not strict requirements (as defined in ISO 9001) but are, nonetheless, valuable contributions to the success of the organization, and should therefore be considered for inclusion in the management system.

The process approach and system design

Another fundamental change is that we are now expected to adopt a process approach to quality management and build our management system around our processes. This has the benefit of making us think closely about the nature of our operation and forces us to take an overview of all the activities and consider how they interact with each other.

The structure of the previous standard actually lent itself to an ad hoc approach to quality system building. We were all familiar with the 20 paragraphs and, many of us, in designing our systems, simply started at the top and drafted out the paperwork we felt was appropriate for each paragraph.

We then put the paperwork in one or more manuals, to which we gave appropriate names, and then started to keep the records. That done, there was no further impediment to having the certificate hanging on the wall in the reception area. At that point, the total objective had often been reached and, thereafter, ISO 9000 was entirely a chore; ISO 9000 had, itself, become the objective.

The 2000 version makes designing a quality management system a more complicated affair. There is no simple checklist of 20 main requirements. The user is forced to stand back and take a look at the overall situation within the organization. Remarkably, many companies have been operating quality management systems to ISO 9000 without having undertaken this rather fundamental task.

With the 20-element checklist, the skeleton of a quality management system was handed on a plate to us and, unfortunately, many of us looked no farther, but merely made our way down through the list making out a few procedures and a record sheets for each element. Our internal audit then consisted of simply making sure that those procedures were followed and the record sheets filled in. And then we then complained that ISO 9000 was not really doing anything for us!

An opportunity for a fresh start

While most of us will complain about the amount of work involved in bringing our systems into line with the requirements of the new standard, we can reflect that it actually provides us with an opportunity to improve our systems, which we might otherwise have never done.

Implementing ISO 9000:2000

Matt Seaver is author of the book *Implementing ISO 9000:2000,* recently published by Gower (**www.gowerpub.com**). The book is intended as a practical guide to setting up a broad-based quality management system that meets the requirements of ISO 9001:2000. It contains a detailed commentary on each of the clauses of ISO 9004:2000, which is designed to facilitate best practice throughout the organization, and guidance on implementing ISO 9001 in a simple and practical manner.

The specific requirements of ISO 9001 are addressed in detail and advice is given on how to implement simple procedures that will be beneficial to the user, as well as complying with the requirements.

Implementing ISO 9000:2000 covers the implications of ISO 9001 for small and medium-sized enterprises and those in the service sector, as well as the larger manufacturing companies.

Included are a comprehensive set of sample procedures and record sheets for the various aspects of a quality management system, plus guidance on how to determine whether they are necessary in any given case, and how they can be modified to suit the circumstances.

The original system may have been based purely on external advice. At the time, we may have had very little insight into the standard or understanding of what it was trying to achieve. We were therefore highly dependent on the quality of the advice we received. Unfortunately, it has to be said that often the advice given was defective, if not downright wrong.

We are probably more conversant with the standard now, more critical of what to expect from it and less likely to allow any expert to force us to implement tasks that do not have any identifiable benefits. We now have a chance to carry out some surgery on the redundant and ineffective parts of the system and convert it into something that will deliver real and measurable benefits. ■

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