Chapter 10

Establishing a Quality Management System

CHAPTER PREVIEW

This chapter is aimed primarily at those with responsibility for developing the organization's management system or assisting with its development such as quality managers and consultants. However, it will also be of interest to those senior managers who decided to adopt ISO 9001 as the basis for assessing the capability of their management system so as to provide an insight into the work involved.

As stated in ISO 9001:2008, Clause 0.1, the adoption of a quality management system should be a strategic decision of an organization, thus implying that organizations have a choice. If you have entered this chapter after reading previous chapters you will be aware that all organizations have a management system whether or not they adopt one. This is because the system is the way the organization functions. A strategic decision that does need to be made is whether to adopt a particular approach for the management of quality and whether to use ISO 9001:2008 as a means to demonstrate its commitment to quality to its stakeholders. If it has been decided to use ISO 9001:2008 in this way, it is important that these decision makers understand what is involved.

In this chapter we examine the requirements in Clause 4.1 of ISO 9001:2008 for establishing a quality management system in terms of what they mean, why they are necessary and how compliance can be demonstrated and in particular:

- The determination of processes;
- The sequence and interaction of processes;
- The criteria and methods for effective operation and control;
- Information and resource availability (see also *Determining and providing resources* in Chapter 19);
- Measuring, monitoring and analysing processes (see also *Measuring and monitoring of products and processes* in Chapter 31);
- The management of processes;
- System implementation;
- System maintenance;
- Continual improvement (see also *Continual improvement* in Chapter 35);
- Outsourcing.

These requirements are repeated in other sections in more detail as denoted in parenthesis. As the documentation requirements are split between sections 4.1 and 4.2 we have consolidated these into the next chapter for convenience.

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MANAGEMENT SYSTEM DEVELOPMENT (4.1)

The standard requires the organization *to establish a quality management system in accordance with the requirements of ISO 9001.*

What Does this Mean?

To *establish* means to set up on a permanent basis, install, or create and therefore in establishing a management system, it has to be developed, resourced, installed and integrated into the organization.

Establishing a system in accordance with the requirements of ISO 9001 means that the characteristics of the system have to meet the requirements of ISO 9001. However, the requirements of ISO 9001 are not expressed as system requirements of the form 'The system shall …' but are expressed as organization requirements of the form 'The organization shall …'. It would appear, therefore, that the system has to cause the organization to comply with the requirements and this will only happen if the system is the organization. Some organizations regard the management system as the way they do things but merely documenting what you do does not equate with establishing a system for the reasons given in *Approach to system development* in Chapter 6.

Why is this Necessary?

This requirement responds to the System Approach Principle.

ISO 9001 contains a series of requirements which if met will provide the management system the capability of supplying products and services that satisfy the organization's customers. All organizations have a management system – a way of working, but in some it is not formalized – in others it is partially formalized and in a few organizations the management system really enables its objectives to be achieved year after year. In some organizations, a management system has been established rather than allowed to evolve and if an organization desires year after year success, it needs a formal mechanism to accomplish this – it won't happen by chance. This requires management to think of their organization as a system as a set of interconnected processes that include tasks, resources and behaviours as explained under *Systems approach vs process approach* in Chapter 7.

How is this Demonstrated?

The terms 'establish', 'document', 'implement', 'maintain' and 'improve' are used in the standard as though this is a sequence of activities. In reality, in order to establish a system it has to be put in place and putting a system in place requires a number of interrelated activities. These can be grouped into four stages of a System Development Project as outlined below. These are consistent with the requirements of Clause 4.1

Addressing Requirements

In addressing the requirements of ISO 9001 it is not necessary for you to use the same wording as in the standard. It is the intent of a requirement that should be addressed in one way or another. An Exposition or Compliance table can provide a translation between the standard and your system (see Chapter 30).

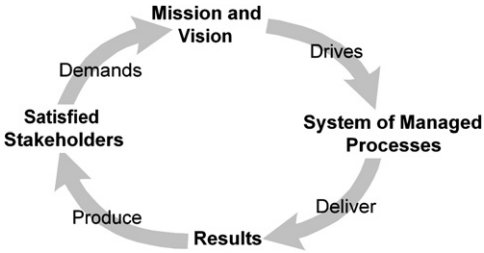

FIGURE 10-1 Cycle of sustained success.

and of Clause 2.3 of ISO 9000:2005 that addresses the Systems Approach. What you have to remember is that you are more than likely not starting from scratch. A system already exists, if it didn't, you and many others would not be working in the organization. Therefore, your task is to reveal this system and in doing so, identify opportunities for improvement. When developing a management system you should have in your mind the cycle of sustained success as shown previously in Chapter 7 and again in Fig. 10-1. Clearly the input to the system of managed processes is the mission and vision with an output of delivering results that produce satisfied stakeholders.

You can demonstrate that you have established an effective system by answering the following questions. The order of the questions is not indicative of a sequence in which an organization is established even though you may be viewing the organization as a system. It is also an iterative process therefore as answers to questions emerge it may cause you to rethink answers already given.

Establish the Goals

By goals we mean the direction in which the organization is going and how it is planning to get there. This is expressed in a number of ways.

1. Ask what is the organization trying to do and in response present the **Mission** statement (see *Ensuring policy is appropriate* in Chapter 15).
2. Ask who are the organization's beneficiaries and in response present a list of **Stakeholders** (see *Identifying the stakeholders* in Chapter 3).
3. Ask what the stakeholder's needs and expectations are relative to the mission and in response present the **Business Outcomes** identified in the Stakeholder Analysis (see *Determining processes* below).
4. Ask what will the stakeholders look for to assess if their needs and expectations have been met and in response present the **Stakeholder success measures or KPIs** as part of the stakeholder analysis (see *Determining processes* and also *Expressing quality objectives* in Chapter 16).
5. Ask what outputs will deliver successful outcomes and in response present the **Business Outputs** (see *Determining processes* below).
6. Ask what limits our ability now or in the future to deliver these outputs and in response present the **Strategic issues** (see under *Quality objectives* in Chapter 16).
7. Ask in what area are we going to concentrate our resources, which segment of the market, with what products, what services and with what values are we going to be

the leader and in response identify the **strategy** (see *Strategic planning* in Chapter 16).

8. Ask what should the organization look like as it successfully implements its strategies and fulfils its mission and in response establish its **Vision**? (see also *Establishing quality policy* in Chapter 15).

Model the Processes

9. Ask what factors affect our ability to deliver the business outputs and in response present the critical activities and results, i.e., the **Critical Success Factors** (see *Determining processes* and also Chapter 37).
10. Ask which processes deal with these factors and in response present the **enabling processes** (see *Determining processes*).
11. To identify the generic business processes ask 'what contribution do this enabling process makes to the business' and in response present the **Business Processes** and their associated sub-processes (see *Determining processes*).
12. Ask what measures will reveal whether the business process objectives have been met and in response present the vision, translated into **process measures**.
13. Ask what provisions have been built into the process design to prevent these processes failing to deliver the required outputs and in response present the **preventive action plans** (see *Determining processes*).

Measure and Analyse Performance

14. Ask to what extent do the organization's products and services satisfy the needs and expectations of customers and in response present the results of **customer satisfaction surveys** (see Chapter 29).
15. Ask what results these processes are delivering and in response present an **analysis of performance** showing actual performance against the KPIs (see Chapters 29 and 34).
16. Ask what methods of measuring customer satisfaction and process capability are used and how often measurements are taken and in response present the **measurement methods** (see *Measuring and monitoring* in Chapter 31).
17. Ask how the integrity of these measurements is assured and in response present **calibration and/or verification records** (see *Control of measurement and monitoring equipment* in Chapter 32).
18. Ask what checks are carried out to verify that processes are operating as planned and in response present the results of **process audits** (see *Internal audit* in Chapter 30).
19. Ask what analysis is performed to determine whether the objectives are being achieved in the most effective way and in response present the results of **process studies** (see *Analysis of data* in Chapter 34).
20. Ask what analysis is performed to determine whether the objectives being achieved remain relevant to stakeholder needs and in response present the results of a recent **Stakeholder analysis** (see *Quality objectives* in Chapter 16 and *Customer satisfaction* in Chapter 29).

Review and Improve Capability

21. Ask what changes have been made as a result of reviewing the data analysis to bring about improvement by better control and in response present the result of **corrective and preventive actions** (see Chapters 36 and 37, respectively).
22. Ask what changes have been made as a result of reviewing the data analysis to improve process efficiency and in response present the results of **continual improvement** (see Chapter 35).
23. Ask what changes have been made as a result of reviewing the data analysis to improve system effectiveness and in response present the results of **management reviews** (see Chapter 18).

Answers to these 23 questions will demonstrate the extent to which you have established an effective quality management system.

DETERMINING PROCESSES (4.1a)

The standard requires the organization *to determine the processes needed for the quality management system and their application throughout the organization.*

What Does this Mean?

Processes produce results of added value. Processes are not procedures (see *Processes versus procedures* in Chapter 8). The results needed are those that serve the organization's objectives. Processes needed for the management system might be all the processes needed to achieve the organization's objectives and will therefore form a chain of processes from corporate goals to their accomplishment. The chain of processes is a *value chain* and therefore should extend from the needs of the stakeholders to the satisfaction of these needs. This is illustrated by the system model of Fig. 7-15.

The change in the 2008 edition from 'identity processes' to 'determine processes' is a change in intent. With the term 'identify' in this context, it could be interpreted that all one had to do was to give a series of existing processes an identity, a label, whereas the intent is to decide, lay down, declare or conclude from reasoning what processes are needed to deliver certain outputs.

The phrase 'needed for the quality management system' in this requirement implies that there are processes that are needed for other purposes. It also implies that the quality management system is something that needs processes rather than something that describes processes. The phrase is ambiguous and needs rewording. A note in Clause 4.1 does not shed any light on the matter as it simply suggests that these processes include processes for management activities, provision of resources, product realization and measurement, analysis and improvement which covers most processes but omits the processes needed to create a demand. Process needed for management activities could be anything from strategic planning to redundancy planning.

A better way of expressing the intent would be to say 'determine the processes needed to enable the organization to achieve its objectives and satisfy its customers'. One might go further and suggest it should be 'all stakeholders', but ISO 9001 limits requirements to customers as one of the stakeholders whereas ISO 9004 addresses all stakeholders.

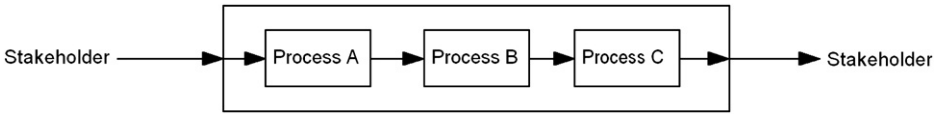

FIGURE 10-2 End-to-end processes.

Published interpretation RFI 029 (see published interpretations in Chapter 4) states that the expression 'needed for the QMS' in Clause 4.1a does not limit the processes to product realization only. Traditionally work has been organized into functions of specialists, each performing tasks that serve functional objectives. By thinking of the organization as a collection of interacting processes rather than a series of interconnected functions, each focused on the needs of stakeholders, the chain of processes cuts across the functions. This is not to say that functions are unnecessary but we must recognize that work does not only flow through functions, it flows through and across the functions by means of a process. The processes needed for the management system are those processes with a purpose that is aligned to the organization's objectives (Fig. 10-2).

As illustrated in Table 8-5, the processes identified in the Generic System Model clearly show the same stakeholder at each end.

Why is this Necessary?

This requirement responds to the Process Approach Principle.

The management system consists of a series of interacting processes and therefore these processes need to be determined.

How is this Demonstrated?

As the standard is not specific to the types of processes, we must assume it is all processes and this would therefore include both business processes and work processes. This distinction is important for a full appreciation of this requirement. The relationship between these two types of processes is addressed further in *Types of processes* in Chapter 8.

In many cases, organizations have focused on improving the work processes believing that as a result there would be an improvement in business outputs but often such efforts barely have any effect. It is not until you stand back that the system comes into view. A focus on work processes and not business processes is the primary reason why ISO 9001, TQM and other quality initiatives fail. They resulted in sub-optimization – not optimization of the organizational performance. If the business objectives are functionally oriented, they tend to drive a function-oriented organization rather than a process-oriented organization. Establish process-oriented objectives, measures and targets, focused on the needs and expectations of external stakeholders, the functions will come into line and you will be able to optimize organizational performance. When Texas Instruments re-engineered its processes in 1992, their process map showed only six processes.[1] Hammer remarks that hardly any company contains more than 10 or so principle processes.

[1] Hammer, Michael and Champy, James (1993). *Reengineering the corporation,* Harper Business.

There are several ways of determining processes but the three that we will discuss here are the stakeholder method, objectives driven method and activity driven method.

The Stakeholder Driven Method

An approach for aligning the mission, vision and values with the needs of the stakeholders and for defining appropriate performance indicators is a Stakeholder Analysis which goes further than the Balanced Scorecard ⓘ and addresses all stakeholders and links stakeholder needs with the processes that deliver outputs that satisfy them. With this method we determine the processes needed from key performance indicators ⓘ. The questions we ask to reveal the information that will lead us to determining the processes are taken from those detailed above. By way of an example we have analysed a fictional fast food business and presented the results in Table 10-1. The questions asked are included in the heading to each column. This shows a direct link between the stakeholder's needs and the processes that will deliver outputs that satisfy those needs. Although the analysis is quite detailed, it is presented to demonstrate the technique and should not be assumed to be representative of any particular fast food outlet.

This is only part of a full stakeholder analysis as you would also gather information on their judgment about your organization's performance. John Bryson provides a practical approach to stakeholder analysis in *Creating and implementing your strategic plan*[2] but it does not address processes to any depth. The business processes were identified in the *System models* of Chapter 7 and under *Types of processes* in Chapter 8.

Objective Driven Method

The stakeholder driven method provides a close alignment between stakeholder needs and process activities but can be time consuming and difficult to do but well worth while. If the quality management system is to be limited in scope to satisfying customers, you could simply take the business outputs that are derived from customer needs in the stakeholder analysis shown in Table 10-1. Another method is to derive the processes from the strategic objectives, business objectives or project objectives but these will include objectives that serve more than customers. The processes identified in the system or organization model can be regarded as Level 0 implying there are further levels in a hierarchy as shown above. It is important to remember that the purpose of any process is to achieve an objective and therefore whether the objective is strategic such as a vision or mission, or is related to the completion of task such as serving a customer, there is still a process to achieve it. However, if the decomposition reaches a level where to go any further in the hierarchy you would be in danger of noting arm movements, you have gone a level too far.

To identify the processes, sub-process or activities you need to know what objectives need to be achieved or what outputs are required and for this you will need access to the business plans, project plans etc. Objectives are simply outputs expressed differently. For example, if the output is growth in the number of enquires the process objective is to

[2] Bryson John M. (2004) Creating and implementing your strategic plan – A workbook for public and non-profit. Jossey Bass.

TABLE 10-1 Example of Determining Processes from an Analysis of Stakeholder

Stakeholders	Stakeholder needs (business outcomes)	Indicators of stakeholder satisfaction	Outputs that will deliver successful outcomes	Critical success factors	Enabling processes	Related business process
Who are the beneficiaries?	What are their needs relative to the mission?	What will they look for as evidence of satisfaction?	What outputs will deliver successful outcomes?	What factors affect our ability to deliver these outputs?	Which process deals with this factor?	What contribution does this enabling process make to the business?
Investors	A financial return that meets target	Profitability	Positive cash flow	Maintaining demand	Maintain cash flow	Resource management
			Effective business strategy	Commitment to the planning process	Develop strategy	Mission management
			Growth in demand	Attracting customers	Product promotion	Demand creation
	Growth	Sales	Growth in demand		Product promotion	Demand creation
			Keeping ahead of the competition	Market intelligence	Competitor analysis	Demand creation
				Service innovation	Service design	
		Market share	Consumer change in preference	Reputation	Performance review	Mission management
			Food and service quality and price	Value for money	Develop pricing strategy	Demand creation
				Customer satisfaction	Service design	Demand creation
					Service delivery	Demand fulfilment

Employees	Competitive pay and conditions	Staff grievances	Motivated workforce	Leadership	Create internal environment	Mission management
		Accident levels	High safety record	Ergonomics	Serving area design	Resource management
				Management style	Create internal environment	Mission management
		Absenteeism	Low sickness record	Management style		
Customers	Fast, safe and nutritious food	Entry to exit time	Short queue length	Serving area design	Design food outlet	Resource management
				Staff competence	Staff development	
			Adequate dining area capacity	Dining area design	Design food outlet	Resource management
		After effects	Safe food	Living by our values	Store food	Resource management
					Prepare food	Demand fulfilment
					Serve food	
			Food handled hygienically		Staff development	
			Cleanliness of equipment		Staff development	Resource management
		Food taste and texture	Food cooked at the right temperature	Competent staff	Staff development	Resource management
			Food stored in right environment			

Continued

TABLE 10-1 Example of Determining Processes from an Analysis of Stakeholder—cont'd

Stakeholders	Stakeholder needs (business outcomes)	Indicators of stakeholder satisfaction	Outputs that will deliver successful outcomes	Critical success factors	Enabling processes	Related business process
	Safe, clean and hygienic environment	Hazard-free public areas	Efficient design of preparation, serving and dining areas	Competent design agency	Service design	Demand creation
			Clean and dry surfaces	Competent staff	Staff development	Resource management
		Appearance and practices in all areas	Competent staff	Training budget	Staff development	Resource management
	Value for money	Competitiveness	Competitively priced menu	Market intelligence	Determine pricing strategy	Demand creation
			Attractive presentation of fresh food in consistent portions	Container design	Serving area design	Demand creation
				Delivery flow		
				Portion control	Serve food	Demand fulfilment
	Efficient counter service	Waiting time	Well designed serving area	Competent design agency	Serving area design	Demand creation
			Competent staff	Training budget	Staff development	Resource management
		Staff courtesy	Selection criteria	Training budget	Staff development	Resource management

Suppliers	Mutually beneficial relationship	Business continuity	Repeat purchases	Profit margins	Financial planning	Resource management
	Prompt Payment	Payment on or before due date	On-time payment on invoices	Cash flow	Accounts	Resource management
Society	Compliance with statutory regulations and instruments	Compliance	Food handling meets hygiene regulations	Shared values	Prepare food	Demand fulfilment
					Serve food	
			Handling and storage of cleaning fluids meet COSHH regulations		Facility maintenance	Resource management
			Exit doors meet fire regulations			
			Sanitation meets building and public health regulations			
	Corporate and social responsibility	Ethical policies and practices	Decisions implement soundly based ethics policy	Shared values	Create internal environment	Mission management
	A local environmental responsibility	Score on environmental survey	Decisions implement soundly based environmental policy	Management commitment	Waste collection	Demand fulfilment
					Waste disposal	Resource management
	Jobs for those who live in the community	Staff ratios	Locals given preference in selection	Conditions of employment	Recruitment	Resource management
	Support for other traders in the community	Source ratios	Produce sourced from local suppliers	Maintaining profit margin	Purchasing	Resource management

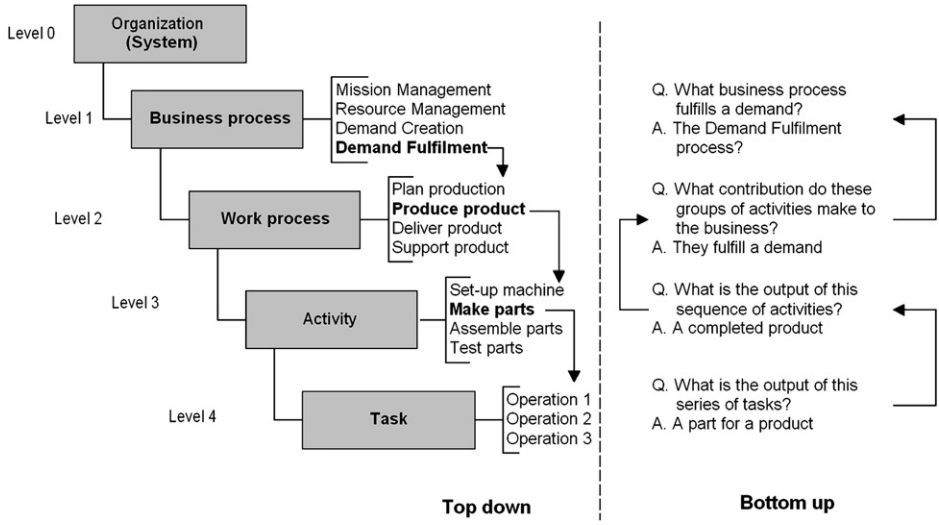

FIGURE 10-3 Process identification (top-down and bottom-up).

grow the number of enquiries. You can then ask a number of questions to determine the processes, sub-process or activities:

1. Ask what processes deliver these outputs or achieve these objectives;
2. Ask what activities produce these outputs or;
3. Ask what affects our ability to deliver these outputs.

The second question may generate different answers to the third question but asking both validates the answers to the second question. If you think you need to do X to achieve Y but when you pose question 3, there is no X in the list, you may have deduced that X is not critical to achieve Y and therefore is not a real process but part of another process.

Starting at Level 1 (see Fig. 10-3) answering question 1 of the business outputs will identify the business processes in the call-out text, e.g., an output of the business is a fulfilled demand therefore a Demand Fulfilment process is needed. Asking question 2 relative to the Demand Fulfilment process will identify the level 2 work processes, i.e., the activities that produce the outputs such as Plan production, produce product. Taking one of these work processes and repeating question 1 we identify level 3 processes such as set-up machine, make parts etc. Answering question 2 of the Make Parts process we identify the individual tasks at level 4.

Let us now suppose that when answering question 2 at level 3 you identified 'inspect' as an activity but when answering question 3 you deduced that making conforming parts was the key factor not inspection, thus inspection was an operation at level 4 and not a process at level 3 (Fig. 10-3).

Activity Driven Approach (Bottom-Up)

Instead of coming at it from objectives you can do it the other way around by identifying a sequence of activities and then:

- Ask "what is the output or objective of this activity" and thereby identify a Stage Output;
- Ask "where does this output go to" and thereby identify the next Stage in the process;

- Follow the trail until you reach the end of the chain of stages with a number of outputs;
- Collect the answers from group to group, department to department and then;
- Ask "what do these groups of outputs have in common" and thereby identify a series of Activity Groups and then;
- Ask "what contribution do these activity groups make to the business" and thereby identify the Business Processes? For example, advertising creates a demand therefore it is part of the Demand Creation Process.

The bottom-up approach involves everyone but has some disadvantages. As the teams involved are focused on tasks and are grouping tasks according to what they perceive are the objectives and outputs, the result might not align with the organizational goals; these groups may not even consider the organization goals and how the objectives they have identified relate to these goals. It is similar to opening a box of components and stringing them together in order to discover what can be made from them. It is not very effective if ones objective is to satisfy the external customer – therefore the top-down approach has a better chance of linking the tasks with the processes that will deliver customer satisfaction.

Case Study – Defining Processes

Some time ago we rewrote all our departmental procedures in the form of flow charts but we are unsure whether these are now documented processes or remain documented procedures as views on this matter differ. When auditing our system to ISO 9001:2008, what will the auditors be looking for to establish that we have actually defined and documented our processes?

When third party auditors ask you to show evidence that you have determined the processes that are needed by the QMS it is not uncommon for them to be satisfied with flow charts that relate to the activities the organization carries out. But from what you say, you took your procedures and rewrote them as flow charts – so in effect they are still procedures; it just so happens that they are now presented in flow chart form rather than text. The mistake you and many auditors make is that you perceive a flow chart to be a process but it appears that you are now prepared to question this logic.

If the charts simply depict activities in some sort of sequence, this would not be a complete process description. One of the problems exacerbated by the surfeit of flow charting tools following the launch of ISO 9001:2000 is that they have put in the hands of system developers a tool that makes every process or procedure look like a flow chart.

Possibly the question should be expressed differently. It is not a question of whether you have documented your processes but whether you have described how particular objectives are achieved or outputs produced. So return to the flow charts you produced and ask:

- Where on this chart does it define the objective that this series of activities is intended to accomplish?
- Where does it show how this objective relates to business objectives?
- Where on this chart does it define how performance of this process is measured, what the measures of success are and who reports the results?
- From which stakeholder does the input come from and the output go to?
- Where on this chart are the human and physical resources required to accomplish this objective?
- Where on the chart does it show where the resources are coming from?
- What changes were made the last time this process was reviewed that improved its performance, efficiency and effectiveness?

If the answer to any of these is 'I don't know?' You have not got an adequate process description.

In every organization there are sets of activities but each set or sequence is not necessarily *a process*. If the result of a sequence of activities adds no value, continue the sequence until value is added for the benefit of customers – then you have defined a *business* or *work process*.

Another technique is IDEF.[3] (Integrated Definition) developed by the US Air Force. The objective of the model is to provide a means for completely and consistently modelling the functions (activities, actions, processes and operations) required by a system or enterprise, and the functional relationships and data (information or objects) that support the integration of those functions. IDEF is a systematic method of modelling that can reveal all there is to know about a function, activity, process or system. Considering its pedigree it is more suited to very complex technical systems but can result in *paralysis from too much analysis!* Many management systems do not require such rigorous techniques. There can be a tendency to drill down through too many layers such that at the lowest level you are charting movements of a person performing an activity or identifying pens and pencils in a list of required resources. For describing the management system processes it is rarely necessary to go beyond a task performed by a single individual. As a rough guide you can cease the decomposition when the charts stop being multifunctional.

SEQUENCE AND INTERACTION OF PROCESSES (4.1b)

The standard requires the organization *to determine the sequence and interaction of the identified processes.*

What Does this Mean?

Sequence refers to the order in which the processes are connected to achieve a given output. Interaction refers to the way the process outputs impact the other processes. A common practice is to represent processes as boxes in a diagram with lines connecting them together. This shows the interconnections in a similar way to a circuit diagram in a TV. If the lines have arrows it indicates the direction of flow for information or product and to some extent the dependencies, the source of inputs and the destination of outputs but not the interactions. Interaction between processes does not have to be shown diagrammatically but Figs 7-13, 9-2 and 9-3 are examples showing interactions.

Why is this Necessary?

This requirement responds to the System Approach Principle.

Objectives are achieved through processes, each delivering an output that serves as an input to other processes along a chain that ultimately results in the objective being achieved. It is therefore necessary to determine the sequence of processes. Some will work in parallel; others in a direct line but all feeding results that are needed to accomplish the objective. There will therefore be interactions between processes that need to be understood.

[3] US Department of Defense (2001). www.idef.com. All IDEF models can be downloaded from this web site.

How is this Demonstrated?

A practical way to show the sequence of processes is to produce a series of flow charts. However, charting every activity can make the charts appear very complex but by layering the charts in a hierarchy, the complexity is reduced into more digestible proportions.

You would start with a System Model similar to that in Fig. 10-4. This shows the relationship between the business processes and the stakeholders. It is a systems view of the organization. You could use the model in ISO 9001 but this is flawed as it identifies the sections of the standard rather than organizational processes. To some extent it also shows the interaction between the business processes but the nature of these interactions is omitted.

If we examine each of these business processes and ask "What affects our ability to deliver the process outputs?" we would identify the key stages, sub-processes or activities. By then placing these in a sequence in which they are executed you create the work processes at level 2. Do the same again for each work process and you create level 3 but this time, there may not be a sequence. Some activities may be activated by time or an event rather than by an input so these can be presented as shown in Figs 10-5 to 10-8. These process models have been derived using the stakeholder driven method in Table 10-1 for the fast food outlet.

All the processes require trained people, equipment and perhaps certain environmental conditions and therefore rely on the resource management process to deliver these outputs. The interface between these processes and resource management process creates an interaction when the processes are active. The reliance on resource management to

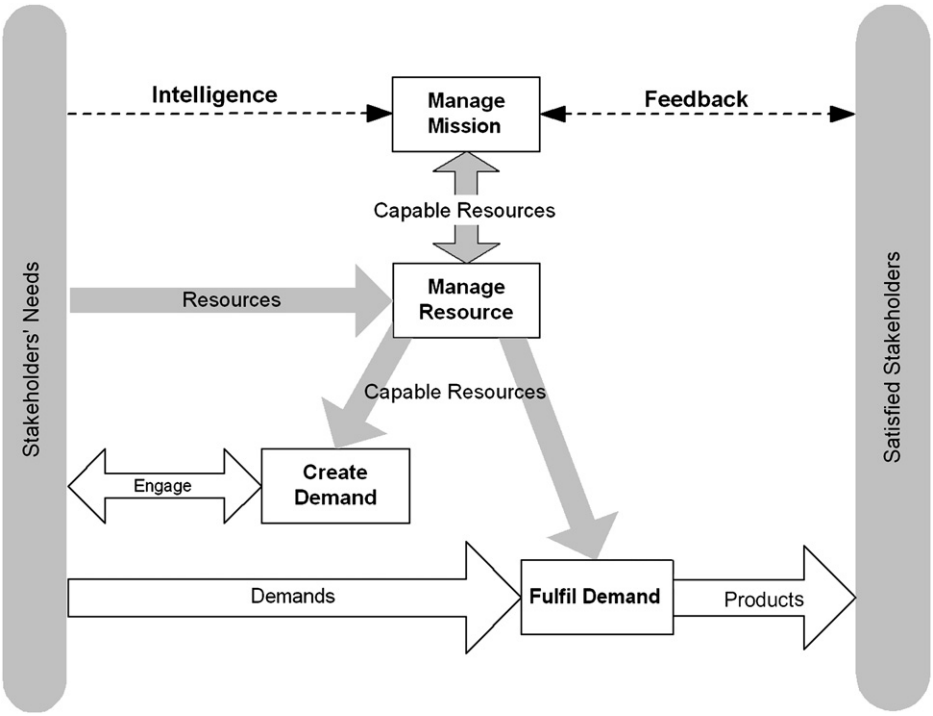

FIGURE 10-4 The generic system model.

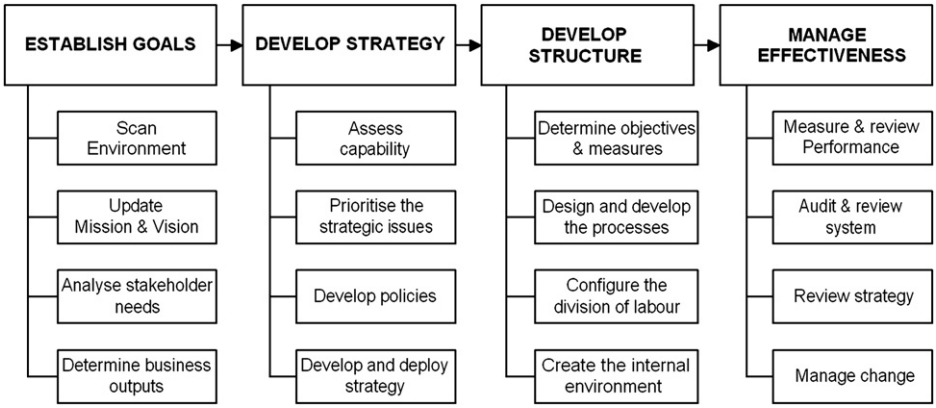

FIGURE 10-5 Mission management process.

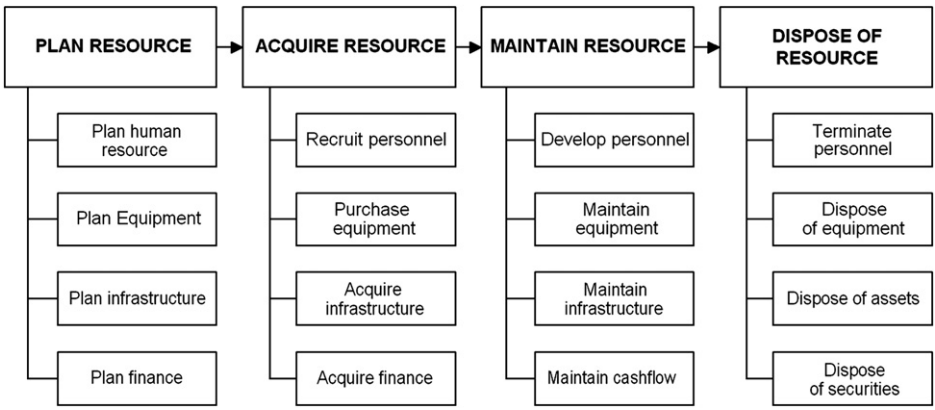

FIGURE 10-6 Resource management process.

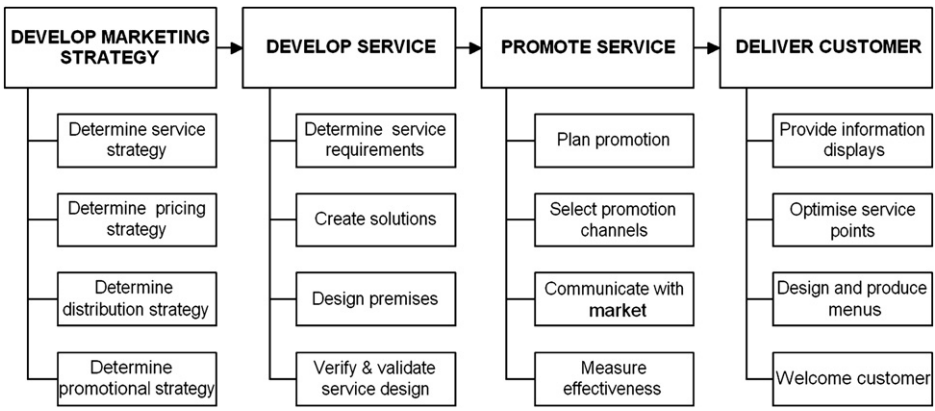

FIGURE 10-7 Demand creation process.

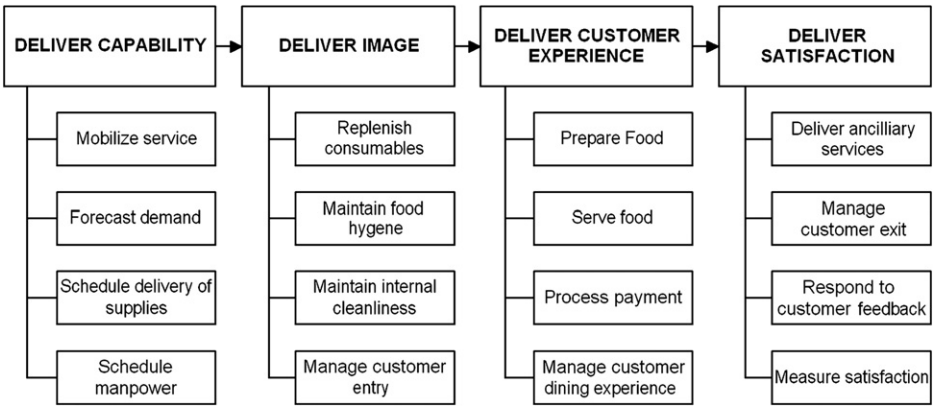

FIGURE 10-8 Demand fulfilment process.

provide inputs creates a dependency. Some of the interactions occur on demand and are therefore dynamic, others are passive and are often taken for granted but without which the process cannot deliver its required output. Analysis is needed to determine the delays in the system that create bottlenecks, the factors that create shortages, the effect of budget cuts on the quality of parts, materials and labour and so on.

CRITERIA AND METHODS FOR EFFECTIVE OPERATION AND CONTROL (4.1c)

The standard requires the organization *to determine criteria and methods required to ensure the effective operation and control of the identified processes*.

What Does this Mean?

The criteria that ensure effective operation are the standard operating conditions, the requirements, targets or success criteria that need to be met for the process to fulfil its objectives.

The methods that ensure effective operation are those regular and systematic actions that deliver the required results. In some cases the results are dependent on the method used and in other cases, any method might achieve the desired results. Use of the word 'method' in this context is interesting. It implies something different than had the standard simply used the word 'procedure'. Procedures may cover both criteria and methods but have often been limited to a description of methods. Methods are also ways of accomplishing a task that are not procedural. For example, information may be conveyed to staff in many ways – one such method might be an electronic display that indicates information on calls waiting; calls completed and call response time. The method of display is not a procedure although there may be an automated procedure for collecting and processing the data.

Why is this Necessary?

This requirement responds to the Process Approach Principle.

A process that is operating effectively delivers the required outputs of the required quality, on time and economically, while meeting the constraints that apply to the

process. A process that delivers the required quantity of outputs that does not possess the required characteristics, are delivered late, waste resources and breach policy and safety, environmental or other constraints is not effective. It is therefore necessary to determine the criteria for the acceptability of the process inputs and process outputs and the criteria for acceptable operating conditions. Thus, it is necessary to ascertain the characteristics and conditions that have to exist for the inputs, operations and outputs to be acceptable.

How is this Demonstrated?

In order to determining the criteria for effective operation and control you need to identify the factors that affect success. Just ask yourself the question: *What are the factors that affect our ability to achieve the required objectives or deliver these outputs?* In a metal machining process, material type and condition, skill, depth of cut, feed and speed affect success. In a design process input requirement adequacy, designer competency, resource availability and data access affect success. In an auditing process, objectives, method, timing, auditor competence, site access, data access and staff availability affect success. There are starting conditions, running conditions and shutdown conditions for each process that need to be specified. If any one of these goes wrong, and whatever the sequence of activities, the desired result will not be achieved.

Determining the methods can mean determining the series of actions to deliver the results or simply identifying a means to do something. For example, there are various methods of control:

- Supervisors control the performance of their work groups by being on the firing line to correct errors.
- Automatic machines control their output by in-built regulation.
- Manual machines control their output by people sensing performance and taking action on the spot to regulate performance.
- Managers control their performance by using information.

The method is described by the words following the word 'by' as in the above list. A method of preventing failure is by performing an FMEA. FMEA® was developed by the aerospace industry in the mid 1960s. You don't have to detail how such an analysis is performed to have determined a method. However, in order to apply the method effectively, a procedure or guide may well be needed. The method is therefore the way the process is carried out which together with the criteria contributes to the description of the process.

ENSURING INFORMATION AVAILABILITY (4.1d)

The standard requires the organization *to ensure the availability of information necessary to support the operation and monitoring of the identified processes*.

What Does this Mean?

Information to support the operation of processes would include that related to:

- Process inputs,
- Planning activities,

- Preparatory activities,
- Result-producing activities,
- Routing activities,
- Process outputs.

Information to support the monitoring of processes would include that related to:

- Past and current performance, throughput, response time, downtime, etc;
- Operating conditions;
- Verification activities;
- Diagnostic activities.

Such information would include plans, specifications, standards, records and any other information required to be used in operating and monitoring the process.

Why is this Necessary?

This requirement responds to the Leadership Principle.

All processes require information whether they are automated or manually operated.

How is this Demonstrated?

Ensuring the availability of information is part of process management and is also addressed above. One would expect personnel to have information available in order to execute their work from preparation to completion.

To ensure availability of information you need to provide access at point of use and this is addressed under the heading *Control of documents*.

ENSURING THE AVAILABILITY OF RESOURCES (4.1d)

The standard requires the organization *to ensure the availability of resources necessary to support the operation and monitoring of the identified processes*.

What Does this Mean?

The resources necessary to support the operation of processes would include:

- Raw materials and consumables;
- Personnel;
- Utilities such as heat, light, power and water;
- Time;
- Equipment, plant machinery, facilities and work space;
- Money to fund the needs of the process.

The resources necessary to support the monitoring of processes would include:

- Instrumentation and equipment;
- Verification and certification services to ensure measurement integrity;
- Personnel to perform monitoring;
- Computers and other tools to analyse results;
- Utilities to energize the monitoring facilities;
- Money to fund the needs of monitoring.

Why is this Necessary?

This requirement responds to the Leadership Principle.

Without the necessary resources, processes cannot function as intended. All processes consume resources. If there are insufficient resources to monitor processes, it is hardly worthwhile operating them because you will not know how they are performing.

How is this Demonstrated?

The process owner or manager is responsible for ensuring the availability of resources. This commences with identifying resource needs, securing an available and qualified supply, providing for their deployment into the process when required and monitoring their utilization. Further guidance is given in *Resource management* in Chapter 6.

MONITORING, MEASURING, AND ANALYSING PROCESSES (4.1e AND 4.1f)

The standard requires the organization *to monitor, measure (where applicable) and analyse the processes and implement actions necessary to achieve planned results.*

What Does this Mean?

Measuring is concerned with determination of the quantities of an entity such as time, speed, and capability indices whereas monitoring is concerned with continual observation aside from periodic measurement. Measuring processes are rather different from measuring the output of processes – this is commonly referred to as inspection or output verification. Figure 10-9 illustrates this difference. Measurement of processes is only required where applicable which means, where the process characteristics are measurable. In reality there will always be a way of measuring performance but it might not always be by using conventional instruments.

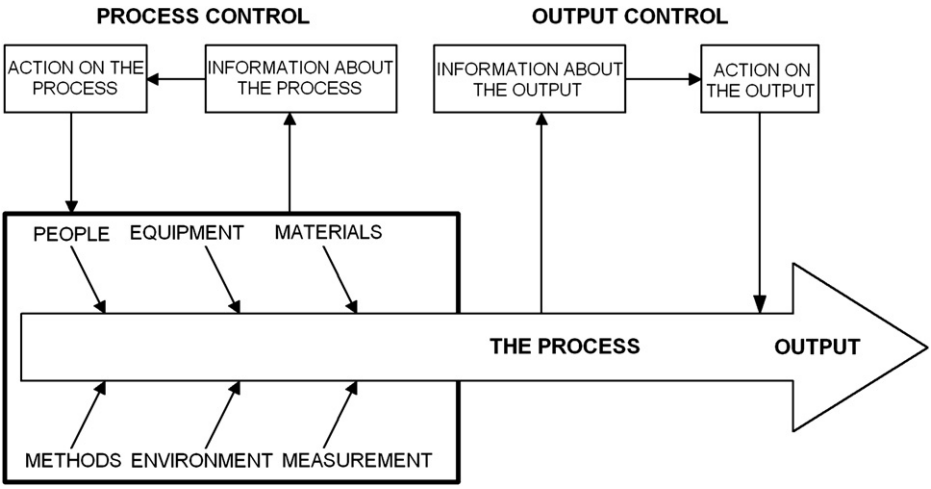

FIGURE 10-9 Process control model.

Analysing processes is concerned with understanding the nature and behaviour of processes for the purpose of their design, development and improvement. Measuring and monitoring take place following installation of the process whereas process analysis can be used as a design tool.

Action necessary to achieve planned results is addressed under *Taking action on process variation* in Chapter 31.

Why is this Necessary?

This requirement responds to the Factual Approach Principle.

You can't manage a process unless equipped with facts about its performance. Observations from monitoring provide this useful information. You cannot claim success, failure or make improvements unless you know the current performance of your processes. It is therefore necessary to install sensors to gather this data. The facts may tell you where you are, but further analysis is needed to establish whether it is an isolated occurrence, an upward or a downward trend and whether improvement is feasible. Process analysis is performed to enable the decision makers to make decisions based on fact.

How is this Demonstrated?

Process Measurement

In order to measure the process you need[4]:

1. Process objectives (what the process is designed to achieve). For example, a sales process may be designed to convert customer enquiries into sales orders and accurately convey customer requirements into the product or service generation process.
2. Indicators of performance (the units of measure). For example, for a sales process measures may be:
   - The ratio of confirmed orders to enquiries;
   - The ratio of customer complaints relative or order accuracy to total orders completed;
   - The ratio of orders lost due to price relative to total order won. Similar indicators could be applied for quality and delivery.

   There may be other indicators related to the behaviour of sales staff in dealing with customers and internal functions such as whether the sales promise matched the true capability of the organization etc.
3. Defined performance standard (the level above or below which performance is deemed to be sub-standard or inferior).
4. Sensors to detect variance before, during or after operations. There may be human or physical sensors, each of which has an element of measurement uncertainty.
5. Calibrated sensors so that you can be assured the results are accurate and precise. There are two types of measurements to be made.
   - Measurements that tell us whether the process is operating as intended;
   - Measurements that tell us whether the process is effective.

[4] Adapted from Juran, J. M. (1995). *Managerial Breakthrough, Second Edition,* McGraw-Hill.

The former measurements are taken using the process indicators and the later measurements are taken using process analysis. Most characteristics will be measurable, if not by variables in terms of mass, length or time, they will be measurable by attributes. (For more on measurement see Chapter 31.)

Process Monitoring

For process monitoring to be effective, the staff involved need to understand the process objectives and how they are measured. They need to be vigilant to potential and actual variations from the norm. A typical type of process monitoring takes place in a ship's engine room where there are lots of dials, gauges and data logging on a continuous basis. The watch engineers scan the log at the start of the watch for unusual occurrences that might account for variation in engine temperature. In monitoring a staff deployment process it may be noticed that staff are trained but there follows prolonged periods before the new skills are deployed. In the invoicing process it may be observed that a number of invoices go missing and have to be resent thus delaying receipt of revenue. In observing the design change process, it may be noticed that there is a burst in activity immediately prior to a holiday period without any additional resources being provided. Monitoring is looking for unusual occurrences or indicators of a potential change in performance.

Process Analysis

Process analysis can be used to implement Clauses 4.1a, 4.1b and 4.1c of ISO 9001 as well as Clause 4.1e and 4.1f.

Analysis in Process Design

Process analysis is performed to design a process and understand its behaviour. In this regard there are a number of activities that may be undertaken and there follows a sequence in which they could be implemented. This can be applied to level 3 activities as shown in Fig. 8-14.

- Define the key performance indicators[i];
- Define the method of measurement;
- Establish current performance against the indicators;
- Produce a process flow chart;
- Perform a task analysis to determine who does what, when, where, how and why;
- Identify constraints on the process and test their validity;
- Perform a control analysis to determine or verify the controls to be/being applied;
- Deploy known customer requirements (e.g., using QFD) to establish that the process will deliver the right output;
- Deploy the constraints (policies, regulations etc.) and identify any gaps;
- Identify failure modes and effects to establish the issues that could jeopardize success;
- Install failure prevention features to reduce, contain or eliminate potential failure modes;
- Conduct relationship analysis to establish conflicts of responsibility and authority and thus potential constraints;
- Perform productivity assessment to identify the number of transactions and their validity;

- Identify resources required to establish any deficiencies;
- Perform information needs analysis to identify or validate all the documentation needed;
- Perform a cultural analysis to establish the behavioural factors that will/are causing success or failure.

This analysis enables decisions to be made on the design or modification of processes and the conditions for their successful operation.

Analysis in Process Operation

In constructing the process, the identified measuring and monitoring stations should be installed. Process analysis is performed on the data generated by these sensors and includes several activities as follows.[5]

- Collect the data from monitoring activities;
- Sort, classify, summarize, calculate, correlate, present, chart and otherwise simplify the original data;
- Transmit the assimilated data to the decision makers;
- Verify the validity of the variation;
- Evaluate the economical and statistical significance of the variation;
- Discover the root cause of the variation;
- Evaluate the alternative solutions that will restore the status quo.

This analysis enables decisions to be made on the continued operation of the processes and whether to modify the conditions under which they operate. (See also under the heading *Taking action on process* v*ariation* in Chapter 31.)

MANAGING PROCESSES (4.1)

The standard requires the organization *to manage the identified processes in accordance with the requirements of ISO 9001.*

What Does this Mean?

Managing these processes in accordance with the requirements of ISO 9001 basically means that the way processes are managed should not conflict with the requirements in other words, managing processes means managing activities, resources and behaviours to achieve prescribed objectives.

The notes to Clause 4.1 of ISO 9001 need some explanation. It is stated that the processes needed for the management system include *management activities, provision of resources, product realization and measurement*. This note could cause confusion because it suggests that these are the processes that are needed for the management system. It would be unwise to use this as the model and far better to determine the processes from observing how the business operates. The term *provision of resources* should be *Resource Management* as addressed previously. *Product realization* is also a collection of processes such as design, production, service delivery, etc. *Measurement* is not a single process but a work process, activity or even a task within each process.

[5] Adapted from Juran, J. M. (1995). *Managerial Breakthrough, Second Edition,* McGraw-Hill.

Grouping all the measurement processes together serves no useful purpose except it matches the standard – a purpose of little value in managing the organization.

Why is this Necessary?

This requirement responds to the Process Approach Principle.

Desired results will not be achieved by chance – their achievement needs to be managed and as the processes are the means by which the results are achieved, this means managing the processes.

How is this Demonstrated?

The first stage in managing a process is to establish what it is you are trying to achieve, what requirements you need to satisfy, what goals you are aiming at; then establish how you will measure your achievements, what success will look like. If the objective were customer satisfaction, what would the customer look for as evidence that the requirements have been met? Would it be product fulfilling the need, delivered on time and not early, at the agreed price with no hidden costs?

Managing processes is primarily about ensuring that:

- Those involved in the process understand the objectives and how performance will be measured.
- Responsibility for actions and decision within the process is properly assigned and delegated.
- The processes providing the inputs are capable of meeting the demand required by the process.
- The required inputs are delivered when they need to be and are of the correct quality and quantity.
- The resources needed to perform the activities have been defined and conveyed to those who will deliver them.
- The forces that prevent, restrict limit or regulate some aspect of process performance are known and their effect minimized.
- The conditions affecting the behaviour of personnel and equipment are under control.
- The activities deemed necessary to deliver the required outputs and achieve the process objectives are carried out in the prescribed manner.
- Sensors are installed to detect variance in performance.
- The measurements taken provide factual data on which to judge performance.
- Provisions have been made for communicating unusual changes in the inputs, operating conditions and process behaviour and that these provisions are working effectively.
- Reviews are performed to verify outputs meet requirements.
- The causes of variation are determined and actions taken to restore the status quo and prevent recurrence of unacceptable variation.
- Reviews are performed to discover better ways of achieving the process objectives and actions are taken to improve the efficiency of operations.
- Objectives, targets and measures are reviewed and changed if necessary to enable the process to deliver outputs that continually serve the organization's objectives.

IMPLEMENTING A QUALITY MANAGEMENT SYSTEM (4.1)

The standard requires *the organization to implement a quality management system in accordance with the requirements of ISO 9001*.

What Does this Mean?

The notion of implementing a management system seems to imply that the management system is a set of rules, a procedure or a plan. One implements procedures but the management system is far more than a collection of procedures. Also the standard requires a management system to be established and as stated previously, to establish a management system you need to design and construct it and integrate it into the organization. If you were to write a book and put it on a bookshelf, you would not refer to the book being established. Implementation therefore applies to the use and operation of the management system following its construction and integration and is therefore concerned with the routine operation of an already established, documented and resourced system. Effective implementation means adhering to the policies and practices, doing what you say you will do.

Why is this Necessary?

This requirement responds to the Leadership Principle.

It goes without saying that it is necessary to use the management system that has been established because the benefits will only arise from using the system.

How is this Demonstrated?

There is no magic in meeting this requirement. You simply need to do what you said you would do, you have to keep your promises, honour your commitments, adhere to the policies, meet the objectives, improve the processes etc. – in other words manage your processes effectively, simply said but extremely difficult for organizations to do. Even if you documented what you do, your practices are constantly changing so little time would pass before the documents were out of date. A common failing with the implementation of documented practices is that they are not sold to the workforce before they become mandatory. Also, after spending much effort in their development, documented practices are often issued without any thought given to training or to verifying that practices have not in fact been changed. As a result, development is often discontinued after document release. It then comes as a shock to managers to find that all their hard work has been wasted. An effectively managed programme of introducing new or revised practices is a way of overcoming these shortfalls.

MAINTAINING A QUALITY MANAGEMENT SYSTEM (4.1)

The standard requires the organization *to maintain a quality management system in accordance with the requirements of ISO 9001*.

What Does this Mean?

For many working with previous versions of the standard this was interpreted as maintaining documents, but as the management system is the means by which the

organization's objectives are achieved, it clearly means much more than this. Maintenance is concerned with both retaining something in and restoring something to a state in which it can perform its required function. In the context of a management system this entails maintaining processes and their capability and maintaining the organization to deliver that capability.

Why is this Necessary?

This requirement responds to the Process Approach Principle.

Without maintenance any system will deteriorate and management systems are no exception. A lack of attention to each of the factors mentioned above will certainly result in a loss of capability and therefore poor quality performance, financial performance and lost customers. Even to maintain performance a certain degree of improvement is necessary – in fact even raising standards can be perceived as a means of maintaining performance in a dynamic environment in which you adapt or die.

How is this Demonstrated?

In maintaining processes you need to keep:

- reducing variation,
- physical resources operational,
- human resources competent,
- financial resources available for replenishment of consumables, replace worn out or obsolete equipment,
- the process documentation up-to-date as changes in the organization, technology, resources occur,
- space available to accommodate input and output,
- buildings, land and office areas clean and tidy – remove the waste,
- benchmarking processes against best in the field.

In maintaining capability you need to keep:

- replenishing human resources as staff retire, leave the business or are promoted;
- renewing technologies to retain market position and performance;
- surplus resources available for unforeseen circumstances;
- up to date with the latest industry practices;
- refreshing awareness of the vision, values and mission.

Another set of actions that can be used is the Japanese 5-S technique.[6]

1. Seiri (straighten up): Differentiate between the necessary and unnecessary and discard the unnecessary.
2. Seiton (put things in order): Put things in order.
3. Seido (clean up): Keep the workplace clean.
4. Seiketsu (personal cleanliness): Make it a habit to be tidy.
5. Shitsuke (discipline): Follow the procedures.

[6] Imai, Masaaki, (1986). *KAIZEN, The key to Japanese Competitive Success,* McGraw-Hill

CONTINUAL IMPROVEMENT IN THE QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES (4.1 AND 4.1f)

The standard requires the organization *to continually improve the effectiveness of the quality management system in accordance with the requirements of ISO 9001*.

What Does this Mean?

ISO 9000:2005 defines continual improvement as a recurring activity to increase the ability to fulfil requirements. As the organization's objectives are its requirements, continually improving the effectiveness of the management system means continually increasing the ability of the organization to fulfil its objectives.

Why is this Necessary?

This requirement responds to the Continual Improvement Principle.

If the management system is enabling the organization to accomplish its objectives when that is its purpose, why improve? The need for improvement arises out of a need to become more effective at what you do, more efficient in the utilization of resources so that the organization becomes best in its class. The purpose of measuring process performance is to establish whether or not the objectives are being achieved and if not to take action on the difference. If the performance targets are being achieved, opportunities may well exist to raise standards and increase efficiency and effectiveness.

How is this Demonstrated?

If the performance of a process parameter is currently meeting the standard that has been established, there are several improvement actions you can take:

- Raise the standard. For example, if the norm for the sales ratio of orders won to all orders bid is 60%, an improvement programme could be developed for raising the standard to 75% or higher.
- Increase efficiency. For example, if the time to process an order is within limits, identify and eliminate wasted resources.
- Increase effectiveness. For example, if you bid against all customer requests, by only bidding for those you know you can win, you improve your hit rate.

You can call all these actions *improvement actions* because they clearly improve performance. However, we need to distinguish between being better at what we do now and doing new things. Some may argue that improving efficiency is being better at what we do now, and so it is – but if in order to improve efficiency we have to be innovative we are truly reaching new standards. Forty years ago, supervisors in industry would cut an eraser in half in the name of efficiency rather than hand out two erasers. Clearly this was a lack of trust disguised as efficiency improvement and it had quite the opposite effect. In fact they were not only increasing waste but also creating a hostile environment.

Each of the improvement actions is dealt with later in the book and is the subject of continual improvement addressed again in Chapter 35.

There are several steps to undertaking continual improvement[7]

1. Determine current performance.
2. Establish the need for change.
3. Obtain commitment and define the improvement objectives.
4. Organize diagnostic resources.
5. Carry out research and analysis to discover the cause of current performance.
6. Define and test solutions that will accomplish the improvement objectives.
7. Product improvement plans which specify how and by whom the changes will be implemented.
8. Identify and overcome any resistance to change.
9. Implement the change.
10. Put in place controls to hold new levels of performance and repeat step one.

OUTSOURCING (4.1)

The standard requires the organization *to ensure control of any outsourced processes that affects product conformity to requirements and to identify such control within the quality management system*.

What Does it Mean?

In purchasing products and services to the supplier's own specification, the organization is not outsourcing processes or subcontracting. It is simply buying products and services. An outsourced process is one that is managed by another organization on behalf of the parent organization. The most common outsourced processes are manufacturing processes such as fabrication, assembly and finishing processes. But organizations also outsource information technology, human resources, cleaning, maintenance and accounting services. In the extreme, they unwisely outsource the internal auditing process and with it all responsibility. Often it is the activities that are outsourced not the process in its entirety. For a process to be outsourced, the supplier should be given an objective and given freedom to determine how that objective will be met. If the supplier merely performs activities dictated by the organization to the organization's specification it is not a process that has been outsourced but tasks.

The standard requires the type and extent of control to be applied to these outsourced processes to be defined within the quality management system. What this means is that in addition to identifying the outsourced processes in the system description, you need to describe how you manage these processes which will differ from the way ordinary purchases are managed.

Why is this Necessary?

At one time, an organization would develop all the processes it required and keep them in-house because it was believed it had better control over them. As trade became more competitive, organizations found that their none-core processes were absorbing a heavy overhead and required significant investment just to keep pace with advances in

[7] Adapted from Juran, J. M. (1995). *Managerial Breakthrough, Second Edition,* McGraw-Hill

technology. They realized that if they were to make this investment they would diminish the resources given to their core business and not make the advances they needed to either maintain or grow the business. A more cost-effective solution was to put the management of these non-core processes in the hands of organizations for which they were their core processes. However, the organization needs to have control over all the processes required for it to achieve its objectives otherwise it can't be confident that it will satisfy its customers.

How is this Demonstrated?

When managing an outsourced process, the organization is not simply placing orders for products and checking that the products received comply with the requirements but establishing process objectives and verifying that the supplier has developed a process that is capable of achieving those objectives. The processes should have a capability that enables the organization to avoid checking the outputs. All the rigor applied to the internal processes should be applied to the outsourced process. Data on the performance of these processes, their efficiency and effectiveness should be analysed by the organization and measures put in place to cause improvement action should the outcomes of the process not satisfy the organization's objectives.

To demonstrate that these outsourced processes are under control it will be necessary to:

- Define the contractual arrangements with the supplier of the outsourced services including:
  - Key performance indicators,
  - Performance targets for these indicators,
  - Reporting provisions,
  - Access rights to verify operations are proceeding in line with the agreed contractual arrangements,
  - Responsibilities of both parties.
- Show in the organization's budgets that you have provided resources for managing the suppliers as if they were part of your own organization;
- Show that you have assessed the provisions the supplier has made for planning, operating and controlling the process and indicated your approval of these plans;
- Show that the supplier shares the same values as you do with respect to customers' property and quality;
- Show that you are monitoring supplier performance and taking action on deviations;
- Show that you are discharging your obligations to the supplier as defined in the contract.

It is important to remember that when you outsource services, the people doing the work are not paid by you but by your contractor. These workers will do what they are paid to do, not what you expect them to do, as you lost the right to control their work when you outsourced the service.