Chapter 2
Achieving sustaining and improving quality

Talking about goodness is easy; achieving it is difficult.

Chinese proverb

The nature of quality management

We know from the foregoing that quality is a result produced when a need, expectation, requirement or demand is met or satisfied. Something that does not satisfy the need is deemed poor quality and something that meets the need in every way is deemed excellent quality. This result (quality) is what most people try to achieve in whatever they do, in all organizations and families. Most of us want the result of our efforts to satisfy the need, expectation, requirement or demand however it is expressed. So how do we go about it?

Abraham Maslow once remarked, "If the only tool you have is a hammer, everything starts to look like a nail to you." And so it is with quality which is why over the last 50 years or so, several approaches have evolved to *achieve, sustain and improve quality.*

The ISO 9000 definition of *quality management* is *coordinated activities to direct and control an organization with regard to quality*. These activities are further identified as quality planning, quality control, quality improvement and quality assurance. In one respect these four concepts form the pillars of quality management (we address each of these later). Quality planning, quality control, quality improvement forms the Juran Trilogy[1] which Juran regards as universal. Although quality assurance is not in the Trilogy, Juran does address this concept in his Quality Control Handbook[2] but regards it quite rightly as providing confidence to all concerned that the quality function (quality planning,

control and improvement and not a department with the name quality in its title) is being performed adequately.

However, specific techniques have gained the limelight sometimes pushing the basic concepts into the background or even off the stage completely and giving the impression that they are better without necessarily acknowledging that they embody all that was good in the previous approach. There have been a continual refreshment and rearrangement of the same ideas in an attempt to bring about a change in performance when the old ideas have lost their appeal or have failed to realize their potential through a lack of understanding or patience!

There are techniques that focus on a specific aspect of quality management such as Advance Product Quality Planning, quality costs, Just-in-time, quality circles, statistical process control, Design of experiments (DOE), 8D, Measurement Systems Analysis (MSA), and risk assessment techniques such as Failure Mode and Effects Analysis (FMEA) and Hazard Analysis and Critical Control Points (HACCP).

Then there are general models such as, TQC, TQM, ISO 9000, PDCA, Deming's 14 points, Crosby's Zero defects, Kaizen, PDCA, Six Sigma and Process Management that all have similar objectives but approach the achievement of these objectives slightly differently. There is so much overlap that it is not possible to illustrate in a practical way how these models and techniques align with the four pillars of quality management.

Goal management or risk management

When one examines the above approaches, what do we see? Do we see a number of models and techniques that are going to enable us to achieve our goals or do we see a number of models and techniques that are going to help us avoid failure? The first is about goal management and the second is about risk management.

If quality management was about goal management one might expect to find models and techniques covering leadership, strategy, planning, finance, marketing, selling, human resource management, engineering, education, training etc. If it were about risk management one might expect to find models and techniques covering risk assessment, probability theory, control methodologies, problem solving. In fact we do see both types but there are probably more techniques focused on risk reduction than goal achievement. What this shows is the management of quality is still developing and while many management tools and techniques exist they are not necessarily perceived as "quality" tools.

The "goal management" school is characterized by five questions:[3]

1. What are you trying to do?
2. How do you make it happen?

3. How do you know it's right?
4. How do you know it's the best way of doing it?
5. How do you know it's the right thing to do?

The "risk management" school is characterized by five different questions:

1. What could go wrong?
2. How might this affect performance?
3. How is the risk being treated?
4. How do you know the precautions are effective?
5. What action is taken to prevent a recurrence of failure or hazard?

In an ideal world, if we could design products, services and processes that could not fail to give complete satisfaction to all the stakeholders we would have achieved the ultimate goal. Success means not only that products, services and processes fulfil their function but also that the function is what customers' desire. Failure means not only that products, services and processes would fail to fulfil their function but also that their function was not what customers and other stakeholders desired. A gold-plated mousetrap that does not fail is not a success if no one needs a gold-plated mousetrap! An automobile that meets the driver's need but emits harmful gasses into the atmosphere is not a success. A typical example is the pressure being brought to bear on four-wheel drive vehicles in the UK. The belief is that four-wheel drive vehicles are gas-guzzlers and should be banned from the streets in view of their perceived effect on global warming. However, customers would not buy them if they did not satisfy their needs and expectations. Perhaps the manufacturers of such vehicles will bow to the pressure groups and slowly withdraw from the market so that they become increasingly difficult to find and those who do own them will be pilloried by society, just as smokers are in public places.

The introductory Clause of ISO 9001:1994 contained a statement that the aim of the requirements is to achieve customer satisfaction by prevention of nonconformities. (This was indicative of the failure school of thought). It was as though the elimination of nonconformity would by itself lead to satisfied customers. We know better now and this is recognized in the introductory Clause of ISO 9001:2000 which contains the following statement: "This International Standard . . . aims to enhance customer satisfaction through the effective application of the system . . . and the assurance of conformity to customer and applicable regulatory requirements." (This is indicative of the success school of thought although it is somewhat limited to customers. Perhaps a more appropriate aim might have been:

"To enhance customer satisfaction in a manner that satisfies the needs and expectations of all stakeholders through the effective application of the system"

Thus recognizing that it is customers that provide the objectives and the other stakeholders that provide the constraints on how those objectives are achieved.)

In reality you cannot be successful unless you know of the risks you are taking and plan to eliminate, reduce or control them. A unification of these approaches is what is therefore needed for organizations to achieve, sustain and improve quality. You therefore need to approach the achievement of quality from two different angles and answer two questions. What do we need to do to succeed and what do we need to do to prevent failure and harm? Of course if your answer to the first question included those things you need to do to prevent failure and harm, the second question is superfluous.

Quality does not appear by chance, or if it does it may not be repeated. One has to design quality into the products and services. It has often been said that one cannot inspect quality into a product. A product remains the same after inspection as it did before, so no amount of inspection will change the quality of the product. However, what inspection does is measure quality in a way that allows us to make decisions on whether or not to release a piece of work. Work that passes inspection should be quality work but inspection unfortunately is not 100% reliable. Most inspection relies on human judgement and this can be affected by many factors, some of which are outside our control (such as the private life, health or mood of the inspector). We may also fail to predict the effect that our decisions have on others. Sometimes we go to great lengths in preparing organization changes and find to our surprise that we neglected something or underestimated the effect of something. We therefore need other means to deliver quality products – we have to adopt practices that enable us to achieve our objectives while preventing failures from occurring and hazards from jeopardizing performance.

Quality management principles

As explained in Chapter 1, we need principles to help us determine the right things to do and understand why we do what we do. The more prescription we have the more we get immersed in the detail and lose sight of our objectives – our purpose – our reason for doing what we do. Once we have lost sight of our purpose, our actions and decisions follow the mood of the moment. They are swayed by the political climate or fear of reprisals. We can so easily forget our purpose when in heated discussion when it is not who you are, but what you say and to whom you say it that is deemed important. Those people who live by a set of principles often find themselves cast out of the club for saying what they believe. However, with presence of mind and recollection of the reasons why the principles are important for survival, they could just redeem themselves and be regarded as an important contributor.

A quality management principle is defined by ISO/TC 176 as *a comprehensive and fundamental rule or belief, for leading and operating an organization, aimed at continually improving performance over the long term by focusing on customers while*

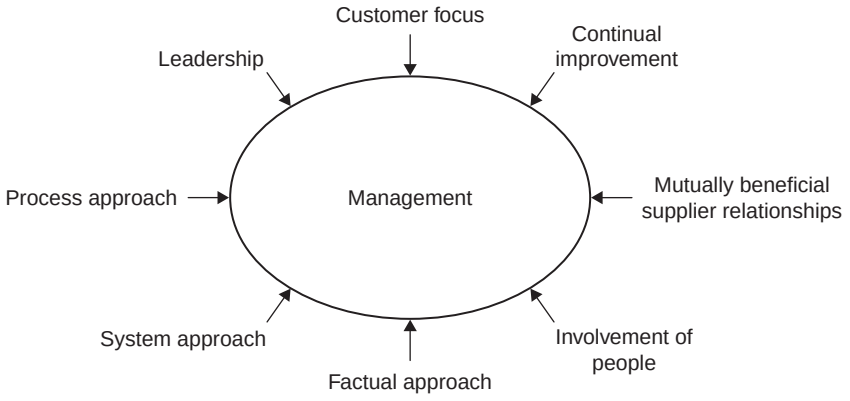

Figure 2.1 The eight quality management principles

addressing the needs of all other interested parties. Eight principles (see Figure 2.1) have emerged as fundamental to the management of quality.

All the requirements of ISO 9001:2000 are related to one or more of these principles. These principles provide the reasons for the requirements and are thus very important. Each of these is addressed below. Further guidance on the application of these principles is provided in *Quality Management Principles*.[4]

Did you know?
Neither the definition of a quality management principle nor the eight principles themselves contain the word QUALITY

Customer focus

This principle is expressed as follows:

Organizations depend on their customers and therefore should understand current and future customer needs, meet customer requirements and strive to exceed customer expectations.

The impact
Inward seeking focus
to
Outward seeking focus

Customers are the lifeblood of every organization. All organizations provide something to others; in fact they do not exist in isolation. We should remember that customers are not simply purchasers but any person or organization that receives a product or service from the organization. Not-for-profit organizations therefore have customers. Customer focus means putting your energy into satisfying customers and understanding that profitability or avoidance of loss comes from satisfying customers. Profit is not the reason for an organization's existence. Profit is needed in order to grow the organization so that it may satisfy more customers. A profit focus is an inward seeking focus; a customer focus is an outward seeking focus. If you focus solely on profit and take your eye off customer needs, you will lose customers and reduce your profits in the long run. Customer focus means

organizing work as a process that converts customers needs into satisfied customers. It means that all processes have a customer focus.

The principle means that everyone in the organization needs to be customer-focused, not simply the top management or the sales personnel. If people were to ask themselves before making a decision, what does the customer need or expect? – the organization would begin to move its focus firmly in the direction of its customers. Customer focus is also about satisfying needs rather than wants. A customer may want ISO 9000 certification but in reality, it is business improvement that may be needed. While an ISO 9001 certificate may appear to give satisfaction initially, this may be short lived as the customer slowly realizes that possession of the ISO 9001 certificate did not result in the growth of business that was expected.

An organization applying the customer focus principle would be one in which people:

- Understood customer needs and expectations.
- Met the needs and expectations of all stakeholders.
- Communicated these needs and expectations throughout the organization.
- Have the knowledge, skills and resources required to satisfy the organization's customers.
- Measured customer satisfaction and acted on results.
- Managed customer relationships.
- Could relate their goals and targets directly to customer needs and expectations.
- Acted upon the results of customer satisfaction measurements.

Leadership

This principle is expressed as follows:

The impact
Aggravation
to
Motivation

Leaders establish unity of purpose and direction for the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Leaders exist at all levels in an organization and they are not simply the ones at the top. Within every team there needs to be a leader i.e. one who provides a role model consistent with the values of the organization. It is the behaviour of leaders (our role models) that influence our lives – not just in the business world but also in our family and leisure activities. People naturally concentrate on what they are measured. It is therefore vital that leaders measure the right things. Without a good leader an organization will go where the tide takes it, and as is so predictable with tides, they will be cast on the shoreline like the flotsam and jetsam of our society. Strong leadership will drive an organization in its chosen direction which is away from disasters but towards success. But leadership alone will not bring the right

success. It needs to be in combination with all the other principles. Leadership without customer-focus will drive organizations towards profit for its own sake. Leadership without involving people will leave behind those who do not share the same vision – hence the second part of the principle. *Leaders are responsible for the internal environment*. If the workforce is unhappy, de-motivated and dissatisfied, it is the fault of the leaders. The culture, vision, values, beliefs and motivation in an organization arise from leadership. Good leadership strives to bring about a set of shared values – a shared vision so that everyone knows what the organization is trying to do and where it is going. A lack of vision and a disparate mix of values create conflict. A happy ship comes about by having good leadership. Regardless of Captain Bligh's orders, the crew's mutiny on the Bounty in 1789 was down to a failure in leadership, which was in fact a failure to create the conditions that motivated people to meet the organization's objectives.

An organization applying the leadership principle would be one in which leaders are:

- Being proactive and leading by example.
- Understanding and responding to changes in the external environment.
- Considering the needs of all interested parties.
- Establishing a clear vision of the organization's future.
- Establishing shared values and ethical role models at all levels of the organization.
- Building trust and eliminating fear.
- Providing people with the required resources and freedom to act with responsibility and accountability.
- Promoting open and honest communication.
- Educating, training and coaching people.
- Setting challenging goals and targets.
- Implementing strategy to achieve these goals and targets.

Involvement of people

This principle is expressed as follows:

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

The impact
Operate
to
Cooperate

It is not uncommon for those affected by decisions to be absent from the discussions with decision-makers. Decisions that stand the test of time are more likely to be made when those affected by them have been involved. Employees cannot employ a part of a person – they take the whole person or none at all. Every person has knowledge and experience beyond the job that he or she has been assigned to perform.

Some are leaders in the community; some are architects of social events, building projects and expeditions. No one is limited in knowledge and experience to the current job they do. This principle means that management should tap this source of knowledge, encourage personnel to make a contribution and utilize their personal experience. It also means that management should be open and not hide its discussions unless national or business security could be threatened. Closed-door management leads to distrust among the workforce. Managers should be seen to operate with integrity and this means involving the people.

An organization applying the involvement of people principle would be one in which people are:

- Accepting ownership and responsibility to solve problems.
- Actively seeking opportunities to make improvements.
- Actively seeking opportunities to enhance their competencies, knowledge and experience.
- Freely sharing knowledge and experience in teams and groups.
- Focusing on the creation of value for customers.
- Being innovative and creative in furthering the organization's objectives.
- Better representing the organization to customers, local communities and society at large.
- Deriving satisfaction from their work.
- Enthusiastic and proud to be part of the organization.

Process approach

This principle is expressed as follows:

The impact
Procedural approach
to
Process approach

A desired result is achieved more efficiently when related resources and activities are managed as a process.

All work is a process because it uses resources to perform actions that produce results. In the organizational sense, such processes add value to the input. Processes are therefore dynamic, i.e. they cause things to happen. An effective process would be one where the results were those that were required to fulfil the purpose of the organization. Every job involves people or machines equipped with resources performing a series of tasks to produce an output. No matter how simple the task, there is always an objective or a reason for doing it, the consumption of resources and expenditure of energy, a number of constraints that influence the way the work will be performed, a sequence of actions, decisions concerning their correctness, a judgement of completeness and an output which should be that which was expected. The organization exists to create and satisfy customers and other stakeholders therefore the organization's processes must serve the needs of these stakeholders.

A process is as capable of producing rubbish as a procedure is capable of wasting resources – therefore processes need to be managed effectively for the required results to be produced. The process approach to management is therefore not simply converting inputs into outputs that meet requirements but about managing processes effectively.

An organization applying the process approach principle would be one in which people are:

- Establishing what it is they want to do – what objectives they want to achieve or what outputs they want to deliver.
- Establishing measures of success – the factors that will indicate whether the objectives have been achieved or the outputs meet requirements.
- Defining the activities that are critical to achieving these objectives and delivering these outputs.
- Identifying the interfaces between the process and the functions of the organization the external customers, suppliers and other stakeholders.
- Establishing clear responsibility, authority, and accountability for managing the process.
- Defining the resources, information and competences required to deliver the required outputs.
- Identifying and measuring the inputs and outputs of the process.
- Identifying the risks and putting in place measures that eliminate, reduce or control these risks.
- Taking action to eliminate the cause of nonconforming inputs or outputs.
- Taking action to prevent use or delivery of nonconforming inputs or outputs until remedial action has been effected.
- Determining how performance will be measured against the objectives and reducing variation.
- Finding better ways of achieving the process objectives and improving process efficiency.
- Establishing whether the processes objectives remain relevant to the needs of the stakeholders and if necessary changing them.

System approach to management

This principle is expressed as follows:

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

A system is an ordered set of ideas, principles and theories or a chain of operations that produce specific results. To be a chain of operations, the operations need to work together in a regular relationship. Taking a systems approach to management means managing the organization as a system of processes so that all the processes fit together, the inputs and outputs are connected, resources

feed the processes, performance is monitored and sensors transmit information which cause changes in performance and all parts work together to achieve the organization's objectives.

The impact
Functional approach to Systems approach

This view of a system clearly implies a system is dynamic and not static. The system is not a random collection of elements, procedures and tasks but a set of interconnected processes. The systems approach recognizes that the behaviour of any part of a system has some effect on the behaviour of the system as a whole. Even if the individual processes are performing well, the system as a whole is not necessarily performing equally well. For example, assembling the best electronic components regardless of specification may not result in a world-class computer or even one that will run, because the components may not fit together. It is the interaction between parts and in the case of a management system, between processes, and not the actions of any single part or process that determines how well a system performs.

An organization applying the system approach principle would be one in which people are:

- Defining the system by identifying or developing the processes that affect a given objective.
- Structuring the system to achieve the objective in the most efficient way.
- Understanding the interdependencies among the processes of the system.
- Taking into account the needs of all stakeholders when making decisions or taking action.
- Understanding the impact of their actions and decision on the organization's goals and the processes that deliver outputs that are intended to satisfy these goals.
- Establishing resource constraints prior to action.

Continual improvement

This principle is expressed as follows:

The impact
Error correction to Course correction

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

This means that everyone in the organization should be continually questioning its performance and seeking ways to reduce variation, continually questioning their methods and seeking better ways of doing things, continually questioning their targets and seeking new targets that enhance the organization's capability. Performance, methods and targets are the three key areas where improvement is necessary for organizations to achieve and sustain success. This results in

three types of improvement, improvement by better control, improvement by better utilization of resources and improvement by better understanding of stakeholder needs. (See also under *Process management*.)

ISO 9000:2000 defines continual improvement as a recurring activity to increase the ability to fulfil requirements. Improvement is therefore relative to a timescale. If the improvement recurs once a week, once a month, once a year or once every 5 years, it can be considered as "recurring". The scale of the improvement is also relative. Improvement can be targeted at specific characteristics, specific activities, specific products, specific processes or specific organizations. When targeted at a specific characteristic it may involve reducing variation in the measured characteristic. When targeted at specific products it may involve major modification – product upgrade. When targeted at the organization it may involve major re-organization or re-engineering of processes. To appreciate the scope of meaning you need to perceive requirements as a hierarchy of needs. At the lowest level are the needs of the task, passing through to the needs of the product, the needs of the process and ultimately the needs of the organization or system. At each level continual improvement is about improving efficiency and improving effectiveness.

It has become fashionable in certain sectors to use the term "continuous improvement" rather than "continual improvement". Continuous means without breaks or interruption such as continuous stationery. "Continual" means repeated regularly and frequently.

An organization applying the continual improvement principles would be one in which people are:

- Making continual improvement of products, processes and systems an objective for every individual in the organization.
- Applying the basic improvement concepts of incremental improvement and breakthrough improvement.
- Using periodic assessments against established criteria of excellence to identify areas for potential improvement.
- Continually improving the efficiency and effectiveness of all processes.
- Promoting prevention-based activities.
- Providing every member of the organization with appropriate education and training, on the methods and tools of continual improvement.
- Establishing measures and goals to guide and track improvements.
- Recognizing improvements.

Factual approach to decision making

This principle is expressed as follows:

Effective decisions are based on the analysis of data and information.

The impact
Subjective
to
Objective

Facts are obtained from observations performed by qualified personnel using devices, the integrity of which is known. The factual approach to decision making leads us to take certain actions. To make decisions on the basis of facts we need reliable mechanisms for collecting facts such as measurement systems. We need valid methods for interpreting the facts and producing information in a form that enables sound decisions to be made. The factual approach leads us to control activities based on fact rather than opinion or emotion. It means using statistical techniques to reveal information about a process, rather than reacting to variation that is an inherent characteristic of the system. However, used in isolation this principle can be dangerous.

An obsession with numbers tends to drive managers into setting targets for things that the individual is powerless to control. A manager may count the number of designs that an engineer completes over a period. The number is a fact, but to make a decision about that person's performance on the basis of this fact is foolish, the engineer has no control over the number of designs completed and even if she did, what does it tell us about the quality of the designs? Nothing! Each design is different so the time to complete each one varies. Each customer is different so the time taken to establish customer needs varies. Setting a target for the number of designs to be completed over a period might lead to the engineer rushing them, injecting errors in order to fulfil a meaningless target. It is therefore necessary to approach the decision in a different way. Firstly decide what decision you want to make and then determine what facts you need in order to make the decision. When you know what facts you need, determine how such facts will be obtained and what methods need to be used to obtain them. Assess the risks of the information being bogus or invalid and put in place measures to ensure its integrity. Work backwards from the decision you need to make to the information you require, not forward from the information to a decision you might make with it. This gives data collection a purpose; for without purpose, data collection is a waste of resources. Don't collect data for the sake of it, just because you can on the pretext that it might come in useful.

An organization applying the factual approach principle would be one in which people are:

- Taking measurements and collecting data and information relevant to the objective.
- Ensuring the data and information are sufficiently accurate, reliable and accessible.
- Analysing the data and information using valid methods.
- Understanding the value of appropriate statistical techniques.
- Making decisions and taking action based on the results of logical analysis balanced with experience and intuition.

Mutually beneficial supplier relationships

This principle is expressed as follows:

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

The impact
Adversarial approach
to
Alliance approach

The customer-focus principle drew our attention to the fact that organizations depend on their customers. It is also valid to state that organizations depend on their suppliers. Suppliers provide the materials, resources and often many services that were once provided by internal functions. The organizations of the 21st century are more dependent on their suppliers than ever before. The quest for lower and lower costs with higher and higher performance has caused many organizations to consider the economics of continuing to operate their own support services. There has been a recognition that organizations were trying to be good at everything rather than being good at their core business. This has led to single-function organizations serving many customers where there is entirely mutual dependency. However, there is another reason that has led to stronger supplier relationships.

Over the last 100 years the market for goods and services has changed dramatically. Prior to the 1920s most firms focused on production in the belief that a quality product will sell itself. From the 1920s to the 1950s, many firms focused on selling what they could make regardless of whether the customer actually needed it. From the 1950s to the 1990s the market turned around from a seller's market to a buyers market as customers became more discerning and firms began to focus on identifying customer needs and producing products and services that satisfied these needs. During the last 10 years, customer orientation has been taken one step further by focusing on establishing and maintaining relationships with both the customers and the suppliers.[5] From a simple exchange between buyer and seller, there evolved strategic alliances and partnerships that cut inventory, packaging and most importantly cut the costs of acquiring new customers and suppliers. There is a net benefit to both parties. For the customer, the supplier is more inclined to keep its promises because the relationship secures future orders. There is more empathy, the customer sees the supplier's point of view and vice versa. There is more give and take that binds the two organizations closer together and ultimately there is trust that holds the partnership together. Absent will be adversarial relationships and one-off transactions when either party can walk away from the deal. The partnerships will also encourage better after-sales care and more customer focus throughout the organization (everyone knows their customers because there are fewer of them).

An organization applying the supplier relationship principle would be one in which people are:

- Identifying and selecting key suppliers on the basis of their ability to meet requirements without compromising quality.

- Establishing supplier relationships that balance short-term gains with long-term considerations for the organization and society at large.
- Creating clear and open communications.
- Initiating joint development and improvement of products and processes.
- Jointly establishing a clear understanding of customers' needs.
- Sharing information and future plans.
- Recognizing supplier improvements and achievements.

Using the principles

The principles can be used in validating the design of processes, in validating decisions, in auditing system and processes. You look at a process and ask:

- Where is the customer focus in this process?
- Where in this process is there leadership, guiding policies, measurable objectives and the environment that motivates the workforce to achieve these objectives?
- Where in this process is the involvement of people in the design of the process, the making of decisions, the monitoring and measurement of performance and the improvement of performance?
- Where is the process approach to the accomplishment of these objectives?
- Where is the systems approach to the management of these processes, the optimization of performance, the elimination of bottlenecks?
- Where in the process are decisions based on fact?
- Where is there continual improvement in performance, efficiency and effectiveness of this process?
- Where is there a mutually beneficial relationship with suppliers in this process?

Quality planning (QP)

The ISO 9000 definition states that *quality planning* is part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives. Juran goes further than this and defines quality planning as "The activity of establishing quality goals and developing products and processes required to meet those goals". Putting product and process development in the same definition creates an ambiguity. Although the definition is of quality planning, not product quality planning, the explanation given by Juran is clearly focused on developing product features and the processes needed to produce those product features therefore his definition is not quite as precise as it could be. Each definition is valid in a particular context.

There are two levels of planning – strategic and operational. Strategic quality planning is concerned with establishing the long-range goals of the organization,

its vision, mission, values and the means to reach those goals while operational quality planning is concerned with establishing product goals and the means to reach those goals. The problem we have today with these ideas is that we tend to drop the word quality or perhaps never use it in this context so a Strategic Plan would be no different to a Strategic Quality Plan – just a different label for the same thing simply because everything we do, we do to satisfy a stakeholder and our plan to satisfy a stakeholder would be no different whether we called it a business plan, a strategic plan or a strategic quality plan. Unfortunately, when we add the word *quality* to the label we do change the perceived meaning because of what quality means to different people.

There is a universal sequence of planning activities. (This is a modified version of that appearing in the book *Juran on Quality by Design*.)

1. Establish the goals (i.e. what it is you want to achieve).
2. Identify who is impacted by these goals (i.e. the customers and other stakeholders).
3. Determine the needs of these stakeholders relative to these goals and prioritize those for action.
4. Develop products or services with features that respond to stakeholders' needs.
5. Develop processes able to produce, promote and distribute the product features.
6. Establish process controls and transfer the plans to the operating forces.

There is no single output of such planning. Planning outputs might include Business Plans, New product development plans, Process development plans and subsequent to these, product descriptions expressing all the features and characteristics that have to be achieved and process descriptions expressing all the activities to be performed, the resources needed to perform them and the controls required to maintain the desired standards.

At the highest level in the organization the planning undertaken to develop core business process might be called business system planning or business process development. At operational levels it might be called process mapping and at the tactical level perhaps the planning effort results in procedures and instructions informing staff how to perform a task.

Over the last 30 years or so, Quality Plans have been required primarily on defence contracts but these plans were not of the same type as the above. Quality Plans tend to be limited to defining the processes and procedures that will be employed on a particular project to ensure the deliverables meet contractual requirements. In some cases these plans simply refer to procedures that form part of the documented quality management system. In other cases, the plans address reliability, configuration management and other project disciplines. They often form part of a Project Plan and rarely do they include the

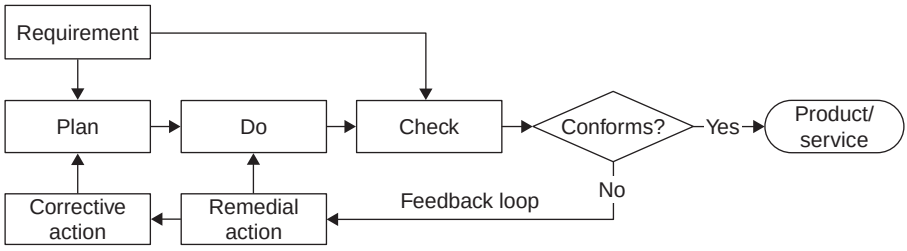

Figure 2.2 Generic control model

product development plans, indicating that quality planning is limited to control and assurance activities.

Quality planning might be a department or section in some organizations either within the quality departments or within production or operations planning. In these cases, the planning is nearly always focused on products and services rather than strategic issues.

Quality control (QC)

The ISO 9000 definition states that *quality control* (commonly abbreviated to QC) is part of quality management focused on fulfilling requirements. What the definition fails to tell us is that controls regulate performance. Control is sometimes perceived as undesirable as it removes freedom, but if everyone were free to do just as they liked there would be chaos. Controls prevent change and when applied to quality they regulate performance and prevent undesirable changes being present in the quality of the product or service being supplied. When operations are under control they are predictable and predictability is a factor that is vital for any organization to be successful. If you cannot predict what might happen when a process is initiated, you are relying on chance. The quality of products and services cannot be left to chance.

The simplest form of quality control is illustrated in Figure 2.2. Quality control can be applied to particular products, to processes that produce the products or to the output of the whole organization by measuring the overall performance of the organization.

Quality control is often regarded as a post-event activity: i.e. a means of detecting whether quality has been achieved and taking action to correct any deficiencies. However, one can control results by installing sensors before, during or after the results are created. It all depends on what you want to control.

The progressive development of controls from having no control of quality to installing controls at all key stages from the beginning to the end of the product cycle is illustrated in Figure 2.3. As can be seen, if you have no controls, quality products are produced by chance and not by design. The more controls you install the more certain you are of producing products of consistent quality but

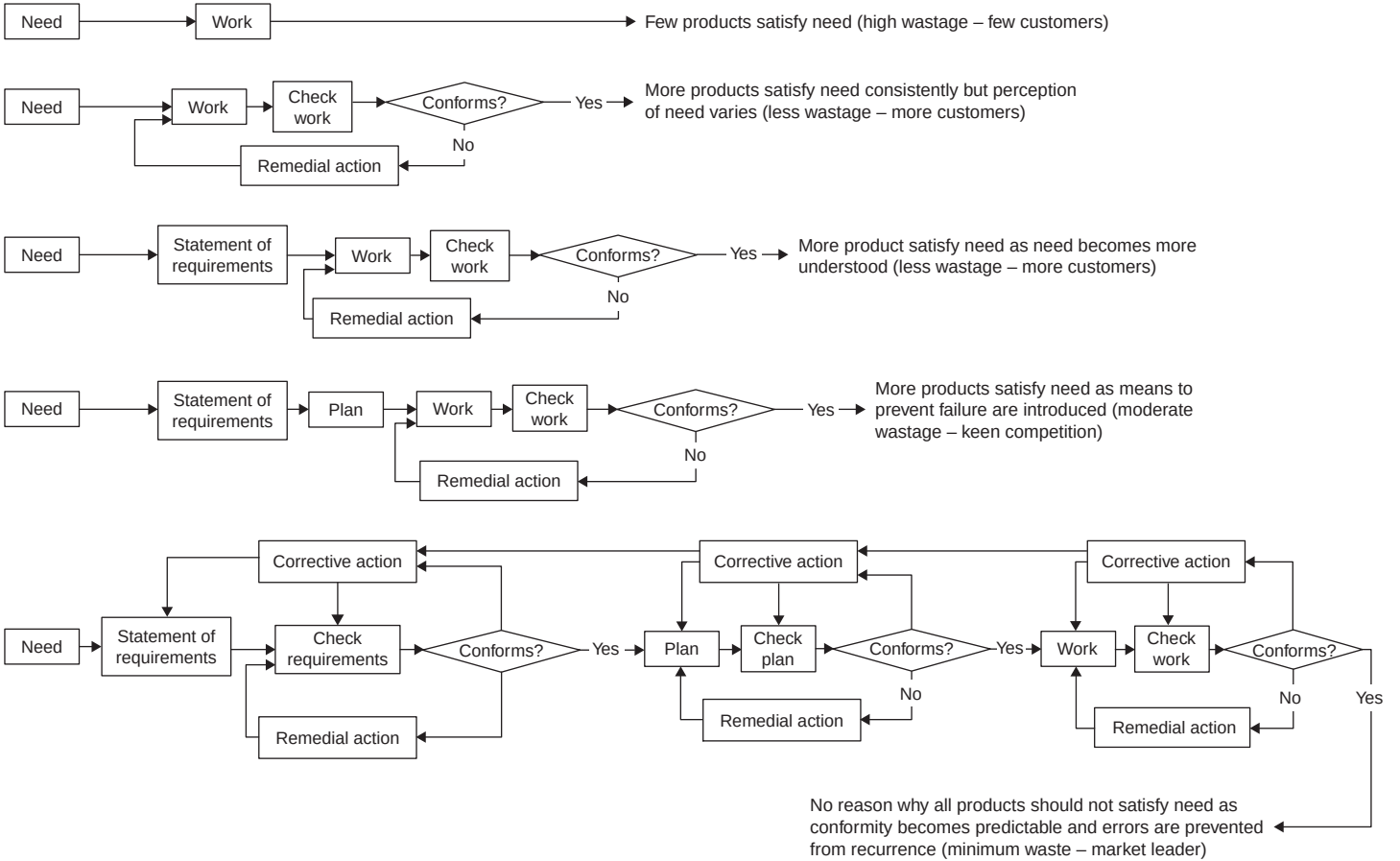

Figure 2.3 Development of controls

more control does not mean more inspection neither does it mean that the checking of work has to be performed by personnel different from those who carried out the work. In Figure 2.3, the work, checks, remedial action and corrective action could well be performed by the same individual. In some cases each task may be performed by different organizations. It rather depends on what the most effective and efficient solution might be for particular organizations.

Control before the event

Some failures cannot be allowed to occur and so must be prevented from happening through rigorous planning and design. One example is the use of reliability prediction performed before the design is complete to predict whether product reliability will meet the specification. Another is the use of competence-based assessment techniques where personnel are under close supervision until they demonstrate competences following which supervisory controls are removed. This allows you to remove output checks because you know that if you were to inspect the work you would find it to be correct. Instead of checking every product produced, you check competency periodically and assign responsibility to personnel for checking their own work. Another method is the use of prevention-based error-proofing mechanisms that sense an abnormality that is about to happen, and then signal the occurrence or halt processing, depending on the severity, frequency or downstream consequences. (This has been referred to as "autonomation", see Appendix A.)

Control during the event

Some failures must be corrected immediately using automatic controls or error proofing. By continuous monitoring of parameters in a processing plant the temperature, pressure, quantities etc., are adjusted to maintain output within specified limits. Electronic components are designed so that they can only be inserted in the correct orientation. Computer programs are designed so that routines will not run unless the correct type of data is entered in every field.

Control after the event

Where the consequences of failure are less severe or where other types of sensors are not practical or possible, output verification can be used as a means of detecting failure early in the process and preventing the subject product passing through subsequent stages and increasing the cost of rectification. Although errors have occurred, measures taken to contain them or remove the defective products from the production stream automatically are another form of error-proofing methods. These are also referred to as leading measures. Product inspection and test is *control after the event* because it occurs after the product is produced but before the product is released out of the organization's control. These are leading measures.

Where failure cannot be measured without observing trends over longer periods, you can use information controls or lagging measures. Many managers receive reports weeks or months after the week in which the deeds were done. Reports produced on long-range frequencies are often only of use to long-range decisions such as setting objectives, policy making etc. They do not stop immediate operations but may well be used to stop further operations when limits are exceeded. The danger in control after the fact is not only the slowness of reporting but also the oscillating effect of any action that is taken. If data on utilization does not reach the manager until weeks after the effort was spent, it is highly likely that when he or she takes action, the demand will have changed and staff will be working overtime to catch up. Observing the overtime the manager recruits more staff but by the time they are operational the demand has reduced once again.

It is often deemed that quality assurance serves prevention and quality control detection, but a control installed to detect failure before it occurs serves prevention, such as reducing the tolerance band to well within the specification limits. So quality control can prevent failure. Assurance is the result of an examination whereas control produces a result. *Quality assurance* does not change the product, whereas *quality control* does.

Quality control as a label

"Quality control" is also the term used as the name of a department. In most cases Quality Control Departments perform inspection and test activities and the name derives from the authority that such departments have been given. They sort good products from bad products and authorize the release of the good products. It is also common to find that Quality Control Departments perform supplier control activities, which are called Supplier Quality Assurance or Vendor Control. In this respect they are authorized to release products from suppliers into the organization either from the supplier's premises or on receipt in the organization.

To control anything requires the ability to effect change, therefore the title Quality Control Department is a misuse of the term, because such departments do not in fact change the quality of the product they inspect. They do act as a regulator if given the authority to stop release of product, but this is control of supply and not of control of quality. Authority to change product usually remains in the hands of the producing departments. It is interesting to note that similar activities within a Design Department are not called "quality control" but "design assurance" or some similar term. "Quality control" has for decades been a term applied primarily in the manufacturing areas of an organization and it is therefore difficult to change people's perceptions after so many years of the term's incorrect use.

In manufacturing, inspection and test activities have been transferred into the production departments of organizations, sometimes retaining the labels and sometimes reverting to the inspection and test labels. However, the term

quality control is used less frequently in the west probably because of the decline of manufacturing. It has not been widely used in the service sector. A reason for this could be that it is considered more of a concept than a function.

Universal sequence of steps

The following steps can accomplish control of quality, or anything else for that matter (Juan J M 1995):

1. Determine the subject of control i.e., what is to be regulated.
2. Define a unit of measure – express the control subject in measurable terms such as quantities, ratios, indices, rating etc.
3. Establish a standard level of performance – a target to aim for.
4. Select a sensor to sense variance from specification.
5. Install the sensor at the stage in the process appropriate to whether you need to control before, during or after results are produced.
6. Collect and transmit data to a place for analysis.
7. Verify the results and establish whether the variance is within the range expected for a stable process (the status quo).
8. Diagnose the cause of any variance beyond the expected range.
9. Propose remedies and decide on the action needed to restore the status quo.
10. Take the agreed action and check that process stability has been restored.

Standards

Without a standard there is no logical basis for making a decision.[6] Within trade and commerce, standards have existed for thousands of years. People needed an equitable basis on which to judge if the fish was fresh, the fruit was ripe, the gold was pure. Standards were needed not only for material things but also for behaviour, for communication, for government. It was necessary to establish a basis for making a comparison between correct and incorrect, right and wrong, good and bad, success and failure. In primitive societies, knowledge of fitness for use was communicated easily and quickly. A trader selling bad meat was soon kicked out of the market. In the modern world such knowledge cannot be communicated as quickly or as reliably or as dependably so it has to be conveyed through documented specifications. The Internet is quick but not necessarily secure or dependable. The written specification becomes a substitute for knowledge of quality and the standard of acceptability. Standards should therefore define the criteria that will indicate whether our performance is acceptable.

In simple terms, standards are the way things ought to be. They are the accepted norms in a society, the acceptance criteria in engineering and the success criteria in process management. We can see evidence of this in our societies. It is what differentiates one country from another. If there were no standards, no norms, nothing would remain the same – not even human body temperature. Imagine if every time you boarded a bus to take you into the city the fare was

different, the driver spoke a different language, the route was different and when you finally arrived and went shopping, you found a size 12 was now a size 21, coffee came in square cups and it tasted more like tea. It would drive you mad. We need stability and standards serve this purpose in our society.

Standards have evolved to enable biological and material things to function and societies to exist in relative harmony.

In the field of quality management standards play a significant role. Standards are what we should be doing. Standards are used to judge whether an output is of good or poor quality. Without any standards we simply have an output of indeterminate quality.

For any quantitative or qualitative parameter there should be a standard value that has been agreed so that a decision can be made following measurement. Taking some examples to illustrate the concept:

- How much should we sell? – The quota is the standard.
- How wide should this shelf be? – The specification is the standard.
- How much can I spend? – The budget is the standard.
- How much time have I got to do this job? – The schedule is the standard.
- How fast can I travel on this road? The traffic signs are the standard.
- What price should we charge? – The market is the standard.
- How should this be performed? The procedure is the standard.
- What error rate is acceptable? The process capability index is the standard.
- How will we make this happen? The plan is the standard.
- Is air travel safe? The latest air accident statistics is the standard.

The way standards are expressed is very important. If standards are expressed poorly we will not be able to confirm conformity therefore standards should be:[6]

- *Attainable* by ordinary people applying themselves with reasonable effort under normal conditions.
- *Economic* to set and administer relative to the activity being addressed.
- *Applicable* to the conditions under which they are to be used.
- *Consistent* in meaning so as to unify communication and consistent in time so as to reflect current knowledge.
- *All-inclusive* by covering all interrelated activities thereby avoiding conflict with activities for which standards have not been set.
- *Understandable* by being expressed in clear, unambiguous and simple terms with no possibility of misinterpretation.
- *Stable* for long enough to provide predictability and amortize the effort in preparing them.
- *Maintainable* so that elements can be added, changed and updated without a complete redesign.
- *Legitimate* by being officially approved by the sponsoring body.
- *Equitable* by being a fair basis for comparison by the people who have the responsibility for meeting them.

Standards are targets to aim for but are also targets to change. If an organization had not managed to lower its product defect rate below 2% for many years, 2% defective becomes the norm and is built into budgets and estimates. Quality improvement takes place when the standard is challenged and a new level of performance achieved.

If standards are to be set and imposed on those responsible for attaining the standard, they need to have the consent of the users. This creates a need for user groups to be formed with participation by representatives of the group of users in the company, sector, region, nation or group of nations. As a result we get company standards, sector standards, national standards etc.

When seeking a standard for a particular quantity, material, product, process or system you can turn to the vast array of national and international standards with confidence that your interests have been represented in the making of these standards and that through periodic review they are maintained current.

Measurement

If the standard defines what we should be doing, measurement tells us what we are doing. Therefore without measurement we really know very little about our performance or the quantity or quality of an output. The control of quality depends on an ability to measure quality be it the quality of products, services, processes, systems, organizations or simply the quality of actions and decisions. Without measurement we won't even know whether we are getting better, getting worse or staying the same. The size of the performance gap shown in Figure 1.3 will not be known.

Measurement is the act of measuring. It is a process of associating numbers with physical quantities and phenomena. Where abstract characteristics such as quality, safety, reliability, courtesy etc. are to be measured, they have to be translated into quantities that can be measured. So for instance if we want to know whether food is safe to eat, rather than get people to sample it, we might count the bugs in it and if the bug count is below a certain level (the standard) we deem it to be safe for human consumption. Therefore, providing the standards are expressed in measurable terms we can measure conformity.

To measure something we need a:

1. Sensor (a detecting device that can be human with or without measuring instruments).
2. Converter if the sensor is not human (a device for converting the signal from the sensor into a form that the human senses can detect).
3. Transmitter where the measurement is done remotely (a device for transmitting the signal to a receiver for analysis).

Sensors need to be accurate, precise, reliable and economic. Sensors that tell lies are of use only to those who wish to deceive. It is too easy to look at a clock, a speedometer, a thermometer or any other instrument and take it for granted

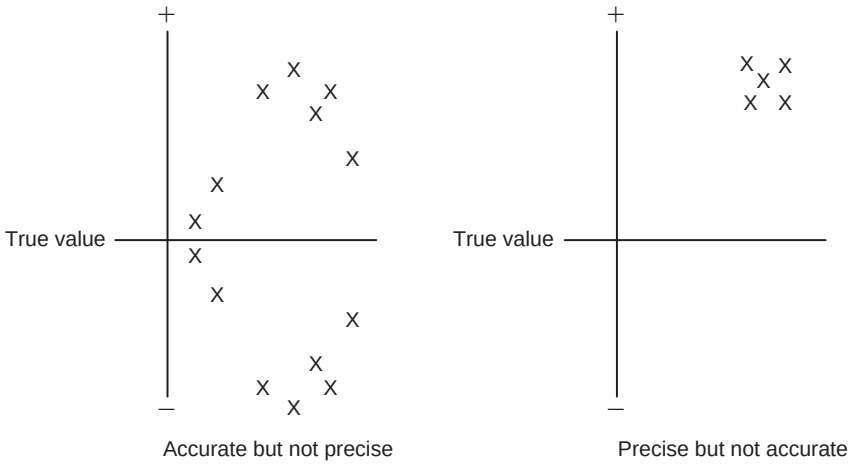

Figure 2.4 Accuracy and precision

that it is telling you the truth. We often put more credence into the readings we get from instruments than we do from our own sensors but both can be equally inaccurate.

Accuracy and precision are often perceived as synonyms but they are quite different concepts. Accuracy is the difference between the average of a series of measurements and the true value. Precision is the amount of variation around the average. So you can have a measuring device that gives a large variation around the true value with repeated measurements but whose average is the true value (see Figure 2.4).

Alternatively you could have a device which gives small variation with repeated measurements around a value which is wide of the true value. The aim is to obtain both accuracy and precision. The difference in accuracy and precision can cause expensive errors. You should not assume that the result you have obtained is both accurate and precise unless the device has been calibrated immediately prior to use and the results of its accuracy and precision provided.

There are two systems used for maintaining the accuracy and integrity of measuring devices – a calibration system and a verification system. The calibration system determines the accuracy of measurement and the verification system determines the integrity of the device. If accuracy is important then the device should be included in the calibration system. If accuracy is not an issue but the device's form, properties or function is important then it should be included in the verification system.

Measurement processes must be in statistical control so that all variation is due to common cause and not special cause. It is often assumed that the measurements taken with a calibrated device are accurate and indeed they are if we take account of the variation that is present in every measuring system and

bring the system under statistical control. Variation in measurement processes arises due to bias, repeatability, reproducibility, stability and linearity.

Bias is the difference between the observed average of the measurements and the reference value.

Repeatability is the variation in measurements obtained by one appraiser using one measuring device to measure an identical characteristic on the same part.

Reproducibility is the variation in the average of the measurements made by different appraisers using the same measuring instrument when measuring an identical characteristic on the same part.

Stability is the total variation in the measurements obtained with a measurement system on the same part when measuring a single characteristic over a period of time.

Linearity is the difference in the bias values through the expected operating range of the measuring device.

It is only possible to supply parts with identical characteristics if the measurement processes as well as the production processes are under statistical control.

In an environment in which daily production quantities are in the range of 1,000 to 10,000 units, inaccuracies in the measurement processes that go undetected can have a disastrous impact on customer satisfaction and consequently profits.

Calibration is a process that has evolved to enable us to establish the accuracy and precision of our measuring devices. It ensures the integrity of measurement but is not limited to physical devices although much of what is written about calibration is concerned with such things. The characteristics of bias, repeatability, reproducibility, stability and linearity in a measuring system are just as relevant when the measuring device is a school examination, a training assessment, a driving test or any other device for assessing the knowledge, skill or competence of personnel to achieve prescribed standards. What value are the results of an examination if a written answer to a question receives widely different marks from different examiners? What value is a college degree if not all recipients are graded using the same measuring process of known integrity?

Variation

Variation is present in all systems. Nothing is absolutely stable. If you monitor the difference between the measured value and the required value of a characteristic and plot it on a horizontal timescale in the order the products were produced, you would notice that there is variation over time. There does not have to be a required value to spot variation. If you monitor any parameter over time (duration, resource consumption, strength, weight etc.) you will see a pattern of variation that with an appropriate scale will show up significant deviations from the average. If you plot the values as a histogram you will observe that there is a distribution of results around the average. As you repeat the plot for a new set of measurements of the same characteristic, you will notice that there

is variation between this second set and the first. In studying the results you will observe variation in:

- The location of the average for each plot.
- The spread of the values.
- The shape of the distribution.

The factors causing these variations are referred to as "assignable" or "special causes".

Special cause

The cause of variations in the location, spread and shape of a distribution are considered special or assignable because the cause can be assigned to a specific or special condition that does not apply to other events. They are causes that are not always present. Wrong material, inaccurate measuring device, worn out tool, sick employee, weather conditions, accident, stage omitted are all one-off events that cannot be predicted. When they occur they make the shape, spread or location of the average change. The process is not predictable while special cause variation is present. Eliminating the special causes is part of quality control – see steps 9–11 above.

Once all the special causes of variation have been eliminated the shape and spread of the distribution and the location of the average become stable, the process is under control – the results are predictable. However, it may not be producing conforming product. You may be able to predict that the process could produce one defective product in every 10 produced. There may still be considerable variation but it is random. A stable process is one with no indication of a special cause of variation and can be said to be in *statistical control*. Special cause variation is not random – it is unpredictable. It occurs because something has happened that should not have happened so you should search for the cause immediately and eliminate it. The person running the process should be responsible for removing special causes unless these causes originate in another area when the source should be isolated and eliminated.

Common cause

Once the special cause of variation has been removed, the variation present is left to chance, it is random or what is referred to as common causes. This does not mean that no action should be taken but to treat each deviation from the average as a special cause will only lead to more problems. The random variation is caused by factors that are inherent in the system. The operator has done all she can to remove the special causes, the rest are down to management. This variation could be caused by poor design, working environment, equipment maintenance or inadequacy of information. Some of these events may be common to all processes, all machines, all materials of a particular type, all work

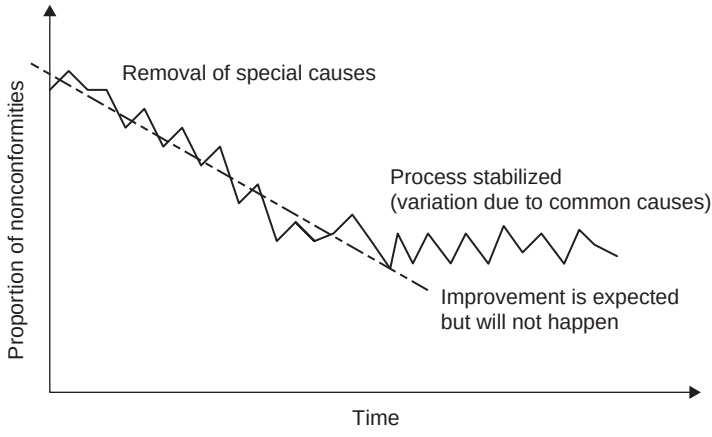

Figure 2.5 Stabilizing processes

performed in a particular location or environment, or all work performed using a particular method. This chain of events is illustrated in Figure 2.5.

This shows that by removing special causes, the process settles down and although nonconformities remain, performance becomes more predictable. Further improvement will not happen until the common causes are reduced and this requires action by management. However, the action management takes should not be to look for a scapegoat – the person whom they believe caused the error, but to look for the root cause – the inherent weakness in the system that causes this variation.

Common cause variation is random and therefore adjusting a process on detection of a common cause will destabilize the process. The cause has to be removed, not the process adjusted. When dealing with either common cause or special cause problems the search for the root cause will indicate whether the cause is random and likely to occur again or a one-off event. If it is random, only action on the system will eliminate it. If it is a one-off event, no action on the system will prevent its recurrence, it just has to be fixed. Imposing rules will not prevent a nonconformity caused by a worn out tool that someone forgot to replace. A good treatment of common cause and special cause variation is given in Out of the Crisis.[7]

With a stable process the spread of common cause variation will be within certain limits. These limits are not the specification limits but are limits of natural variability of the process. These limits can be calculated and are referred to as the Upper and Lower Control Limits (UCL and LCL respectively). The control limits may be outside the upper and lower specification limits to start with but as common causes are eliminated, they close in and eventually the spread of variation is all within the specification limits. Any variation outside the control limits will be rare and will signal the need for corrective action. This is illustrated in Figure 2.6.

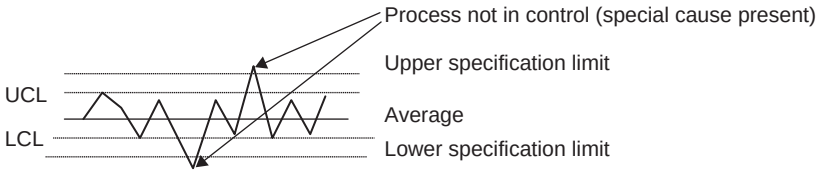

Figure 2.6 Control limits and specification limits

Table 2.1 10 Step process yield

Stage	*Yield/stage*	*Total % yield*	*Initial population 1 million*
1	0.80	80	800,000
2	0.80	64	640,000
3	0.80	51.2	512,000
4	0.80	41	409,600
5	0.80	32.8	327,680
6	0.80	26.2	262,144
7	0.80	21	209,715
8	0.80	16.8	167,772
9	0.80	13.4	134,218
10	0.80	10.7	107,374

Keeping the process under control is process control. Keeping the process within the limits of the customer specification is quality control. The action needed to make the transition from process control to quality control is an improvement action and this is dealt with under Quality improvement.

Six sigma as a statistical concept

In a perfect world, we would like the range of variation to be well within the upper and lower specification limits for the characteristics being measured but invariably we produce defectives. If there were an 80% yield from each stage in a 10-stage process, the resultant output would be less than 11% and as indicated in Table 2.1 we would obtain only 107,374 good products from an initial batch of 1 million.

Even if the process stage yield were 99% we would still obtain 95,617 less products than we started with. It is therefore essential that multiple stage processes have a process stage yield well in excess of 99.99% and it is from this perspective that the concept of six sigma emerges.

The small Greek letter s is σ and is called sigma. It is the symbol used to represent the standard deviation in a population. We use s for standard deviation

as measured by a sample of finite magnitude. Standard deviation is the square root of the variance in a population. In plain English, standard deviation tells us how tightly a set of values is clustered around the average of those same values. In statistical speak, standard deviation is a measure of dispersion (spread or variability) about a mean value (or average) of a population that exhibits a normal distribution and is expressed by the formula:

$$\sigma = \sqrt{\frac{\sum (x - \mu)^2}{n}}$$

where x is a value such as mass, length, time, money, μ is the mean of all values, Σ is capital sigma and is the mathematical shorthand for summation and n is the number in the population.

When the variance is computed in a sample, the formula is:

$$\mathrm{s} = \sqrt{\frac{\sum (x - \overline{x})^2}{n}}$$

where $\overline{x}$ is the mean of the sample and n the sample size.

However, small samples tend to underestimate the variance of the parent population and a better estimate of the population variance is obtained by dividing the sum of the squares by the number of degrees of freedom. Variance in a population thus becomes:

$$\mathrm{s} = \sqrt{\frac{\sum (x - \overline{x})^2}{n - 1}}$$

When the population of a variable is concentrated about the mean the standard deviation is small indicating stability and when the population of a variable is spread out from the mean the standard deviation is large indicating volatility.

When the frequency distribution of a set of values of a variable is symmetrical about a mean it may approximate to a normal distribution represented by the equation:

$$y = \frac{1}{\sqrt[q]{2\pi}} e^{\frac{-(x-\overline{x})^2}{2\sigma^2}}$$

where y is the height of the curve at any point along the scale of x and e is the base of the Napierian logarithms (2.7183) and π the well known ratio of the circumference of a circle to its diameter which to 3 decimal places is = 3.142.

The shape of the normal distribution embraces:

68.26% of the population within ±1 standard deviation around the mean
95.46% of the population within ±2 standard deviations around the mean
99.74% of the population within ±3 standard deviations around the mean and

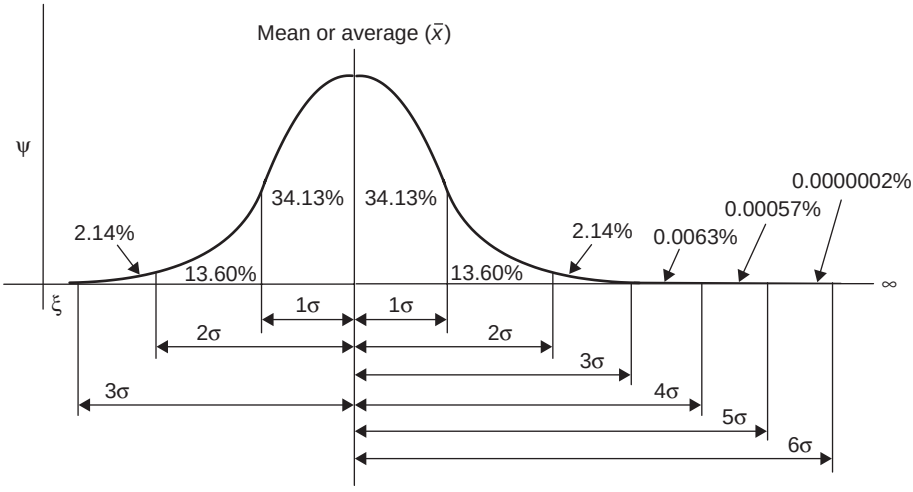

Figure 2.7 Normal distribution and standard deviation

99.9937 of the population within ±4 standard deviations around the mean, which is 100% for most applications. In industries producing millions of products even greater performance is deemed necessary especially when all output is being shipped to one customer. This represented diagrammatically and extended to 6 standard deviations in Figure 2.7.

Assuming a normal distribution of results at the six sigma level you would expect 0.002 parts per million or ppm but when expressing performance in ppm, it is common practice to assume that the process mean can drift 1.5 sigma in either direction. The area of a normal distribution beyond 4.5 sigma from the mean is 3.4 ppm. As control charts will detect any process shift of this magnitude in a single sample, the 3.4 ppm represents a very conservative upper boundary on the non-conformance rate.[8]

Although the concept of six sigma can be applied to non-manufacturing processes you cannot assume as was done in Table 2.1 that the nonconformities in a stage output are rejected as unusable by the following stages. A person may pass through 10 stages in a hospital but you cannot aggregate the errors to produce a process yield based on stage errors. Patients don't drop out of the process simply because they were kept waiting longer than the specified maximum. You have to take the whole process and count the number of errors per 1 million opportunities.

Table 2.2 shows the number of products meeting requirements and the equivalent defects per million products for a range of standard deviations. In Table 2.2, six sigma (6σ) translates into 2 errors per billion opportunities but what Motorola found was that processes drift over time, what they call the Long-Term Dynamic Mean Variation. Motorola judged this variation as typically falling between 1.4 and 1.6 sigma, and will therefore account for special cause variation causing drift over the long term (years not months). Views do appear to differ on why

Table 2.2 Process yield at various sigma values

Sigma	*Product meeting requirements %*	*Number of errors per million products*	
		Assuming normal distribution	*Assuming 1.5 sigma drift*
1	68.26	317400.000	697672.15
2	95.45	45,500.000	308770.21
3	99.73	2,700.000	66810.63
4	99.9937	63.000	6209.70
5	99.999943	0.570	232.67
6	99.9999998	0.002	3.40

the 1.5 sigma drift is applied but in any event in most situations whether six sigma is 2 errors per billion or 3.4 errors per million opportunities matters not to most people – it is only a target.

However, every measurement process, however complicated, has certain underlying assumptions that mean the results are valid only when certain conditions apply.

There are four assumptions that typically underlie all measurement processes; namely, that the data from the process at hand "behave like":

1. Random samples.
2. From a fixed distribution.
3. With the distribution having fixed location; and
4. With the distribution having fixed variation.

If the four underlying assumptions hold, then we have achieved probabilistic predictability – the ability to make probability statements not only about the process in the past, but also about the process in the future. In short, such processes are said to be "in statistical control". Thus attempts at reaching six sigma levels in a process that is not in statistical control will be futile.

Six sigma as a strategic concept

In addition to being a statistical concept, the term Six Sigma is also used to describe a rigorous and disciplined methodology that uses data and statistical analysis to measure and improve a company's operational performance by identifying and eliminating process "defects". In this sense it is a project-based initiative that identifies actual problems and eliminates their cause. A project would be any endeavour to reach six sigma levels in an aspect of performance. These projects are not limited to manufacturing and the techniques can be applied to any process in any organization. The aim is simply to reduce variation so that the number of errors falls to less than 3.4 per million opportunities for each product or service transaction. An "opportunity" is defined as a chance for non-conformance.

When one considers the number of things than go right in an organization it probably runs into millions. If one considers the number of ways a product or service might fail it might run into double digits. If you produce 12,000 units per year and each unit has 500 components that could fail you would have 6 million opportunities for failure.

The Six Sigma methodology is not a revolutionary way of thinking, and it does not provide a radically new set of quality tools. It is more of an evolutionary development in the science of continuous improvement that combines the best elements from many earlier quality initiatives some of which date back more than 50 years.

The label "six sigma" was first given to these improvement techniques in Motorola in about 1987 when they married the concept of process capability and product specifications and began to express process capability in terms of defects per million opportunities (DPMO). As a result of winning the Baldrige Award in 1988, Motorola was compelled to share its quality practices with others. When in 1995 Jack Welsh, the CEO of General Electric (GE) adopted Six Sigma, many organizations took notice and this was followed by an explosion in literature and training on Six Sigma. Like many new initiatives, there is much misunderstanding and of course there is an economic limit to any improvement – absolute zero defects is only free if you put the specification limits well outside the process capability and the process remains capable which of course cannot be guaranteed.

It is interesting to note that Toyota does not have a six sigma programme.[9] They prefer instead to use a seven-step problem solving process.

Six Sigma projects range from tackling a particular problem with the surface finish on a shaft to redesigning both products and business processes.

The steps in a typical Six Sigma programme would be:

- Identify the organization's biggest problems.
- Assign the best people to fix these problems.
- Providing the necessary resources and management support.
- Grant uninterrupted time to work on the problems.
- Undertake the necessary changes that will eliminate the problems.

At its core, Six Sigma revolves around a few key concepts.[10]

Concept	*Description*
Critical to Quality:	Attributes most important to the customer
Defect:	Failing to deliver what the customer wants
Process Capability:	What your process can deliver
Variation:	What the customer sees and feels
Stable Operations:	Ensuring consistent, predictable processes to improve what the customer sees and feels
Design for Six Sigma:	Designing to meet customer needs and process capability

The objective of the Six Sigma methodology is reduction in variation and this is achieved through a prescribed problem solving process called DMAIC (define, measure, analyse, improve, control). By induction and training, staff begin to use this problem solving technique to identify and resolve problems that are preventing the organization from achieving defined targets. Largely because most processes are not designed to be capable, (i.e. not designed to deliver conforming outputs every time), the Six Sigma projects bring about performance improvement by better control. In other words, they bring the process under control so that it delivers conforming output in the manner it should have done when the process was designed. Although manufacturing processes are often designed, non-manufacturing processes are not – they evolve and successive re-organizations only tend to deal with the symptoms not the root causes so using the Six Sigma methodology for non-manufacturing processes can bring about much needed improvement. However, it is no replacement for good process design.

The DMAIC problem solving technique is explained in the panel.

DMAIC Problem Solving Technique (As expressed by GE)

DEFINE

- Define the Customer, their Critical to Quality (CTQ) issues, and the Core Business Process involved.
- Define who customers are, what their requirements are for products and services, and what their expectations are.
- Define project boundaries – the stop and start of the process.
- Define the process to be improved by mapping the process flow.

MEASURE

- Measure the performance of the Core Business Process involved.
- Develop a data collection plan for the process.
- Collect data from many sources to determine types of defects and metrics.
- Compare to customer survey results to determine shortfall.

ANALYSE

- Analyse the data collected and process map to determine root causes of defects and opportunities for improvement.
- Identify gaps between current performance and goal performance.
- Prioritize opportunities to improve.
- Identify sources of variation.

IMPROVE

- Improve the target process by designing creative solutions to fix and prevent problems.
- Create innovate solutions using technology and discipline.
- Develop and deploy implementation plan.

CONTROL

- Control the improvements to keep the process on the new course.
- Prevent reverting back to the "old way".
- Require the development, documentation and implementation of an ongoing monitoring plan.
- Institutionalize the improvements through the modification of systems and structures (staffing, training, incentives).

Restoring the status quo

Corrective action restores the status quo i.e. it brings performance back to where it should have been before the incident of unacceptable variation. Corrective action is the pattern of activities that traces the symptoms of a problem to its cause, produces solutions for preventing recurrence of the problem, implements the change and monitors that the change has been successful. Corrective action provides a feedback loop in the control cycle. Whilst the notion of *correction* implies that it could be as concerned with the nonconforming item as with the cause of nonconformity, correcting the nonconforming item is a remedial action. It doesn't stop it recurring. ISO 9000 does not use the term remedial action except in the context of a repair. Preventing the recurrence of nonconformity is a corrective action. A problem has to exist for you to take corrective action. When actual problems don't exist but there is a possibility of failure, the action of preventing the occurrence of nonconformity (or any problem for that matter) is a *preventive action*. So we have Remedial Action, Corrective Action and Preventive Action, each with a different meaning.

Putting terms in the right order

Preventive action serves to prevent the nonconformity from **occurring**

Inspection detects nonconformity

Nonconformity control identifies, segregates and rectifies the nonconforming item

Corrective action serves to prevent the nonconformity from **recurring**.

Nonconformities are caused by factors that should not be present in a process. There will always be variation but variation is not nonconformity. Nonconformity arises when the variation exceeds the permitted limits. The factors that cause nonconformity on one occasion will (unless removed) cause nonconformity again and again. As the objective of any process must be to produce conforming

output, it follows therefore that it is necessary to eliminate the causes of nonconformity. This does not simply apply to products of the production process but to products of all processes – mission management, demand creation and demand fulfilment.

It is important to distinguish between four separate actions when dealing with nonconformity:

- Action to remove the specific nonconformity in the nonconforming item. This may take the form of return for completion of operations, rework, repair, scrap or temporary change to specification (i.e. a concession).
- Action to discover other occurrences of the nonconformity. The variation may have been discovered in a sample therefore there may be other nonconforming items elsewhere.
- Action to prevent recurrence in the short term (this is the local action taken on the immediate cause and often referred to as "containment action").
- Action to prevent recurrence in the long term (this is the action taken on the root cause and is the only true corrective action).

Quality improvement (QI)

Firstly we need to put *quality improvement* in context because it is a minefield of terms and concepts that overlap one another. There are three things that are certain in this life, death, taxes and change! We cannot improve anything unless we know its present condition and this requires measurement and analysis to tell us whether improvement is both desirable and feasible. Improvement is always relative. Change is improvement if it is beneficial and a retrograde step if it is undesirable but there is a middle ground where change is neither desirable (beneficial) nor undesirable, it is inevitable and there is nothing we could or should do about it. Change is a constant. It exists in everything and is caused by physical, social or economic forces. Its effects can be desirable, tolerable or undesirable. Desirable change is change that brings positive benefits to the organization. Tolerable change is change that is inevitable and yields no benefit or may have undesirable effects when improperly controlled. The challenge is to cause desirable change and to eliminate, reduce or control undesirable change so that it becomes tolerable change. Juran writes on improvement thus "Putting out fires is not improvement of the process – Neither is discovery and removal of a special cause detected by a point out of control. This only puts the process back to where it should have been in the first place".[11] This we call *restoring the status quo*. If eliminating special causes is not improvement but maintaining the status quo, that leaves two areas where the improvement is desirable – the reduction of common cause variation and the raising of standards.

Figure 2.8 illustrates the continuing cycle of events between periods of maintaining performance and periods of change. The transition from one target to another may be gradual on one scale but considered a breakthrough on another

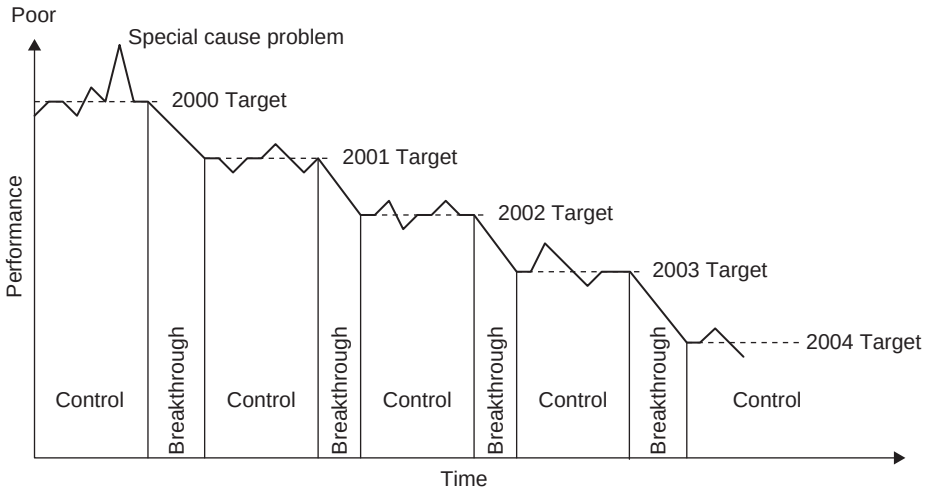

Figure 2.8 Continual improvement

scale. The variation around the target value is due to common causes that are inherent in the system. This represents the expected performance of the process. The spike outside the average variation is due to a special cause, a one-off event that can be eliminated. These can be regarded as fires and is commonly called *fire fighting*. Once removed the process continues with the average variation due to common causes.

When considering improvement by raising standards, there are two types of standards: one for results achieved and another for the manner in which the results are achieved. We could improve on the standards we aim for, the level of performance, the target or the goal but use the same methods. There may come a point when the existing methods won't allow us to achieve the standard, when we need to devise a new method, a more efficient or effective method or due to the constraints on us, we may choose to improve our methods simply to meet existing standards.

This leads us to ask four key questions:

1. Are we doing it right?
2. Can we keep on doing it right?
3. Are we doing it in the best way?
4. Is it the right thing to do?

The ISO 9000 definition of *quality improvement* states that it is that part of quality management focused on increasing the ability to fulfil quality requirements. If we want to reduce the common cause variation we have to act on the system. If we want to improve efficiency and effectiveness we also have to act on the system and both are not concerned with correcting errors but concerned with doing things better and doing different things.

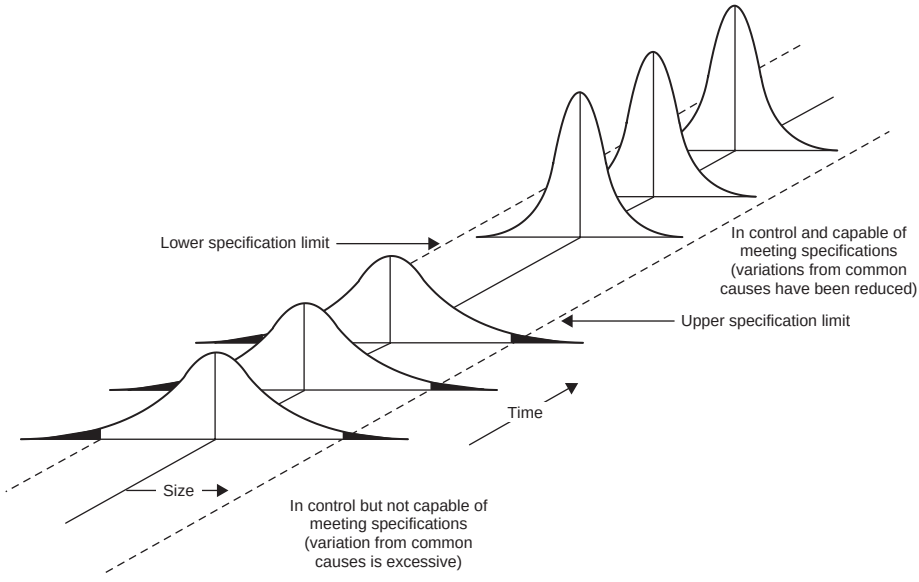

Figure 2.9 From process control to capable process

There is a second dimension to improvement – it is the rate of change. We could improve "gradually" or by a "step change". Gradual change is also referred to as incremental improvement, continual improvement or *kaizen.* "Step change" is also referred to as "breakthrough" or a "quantum leap". Gradual change arises out of refining the existing methods, modifying processes to yield more and more by consuming less and less. Breakthroughs often require innovation, new methods, techniques, technologies and new processes.

Are we doing it right?

Would the answer be this?	No we are not because sometimes we do it we get it wrong and have to do it again.
Or would it be this?	Yes we are because every time we do it we get it right and we never have to do it over again.

Quality improvement in this context is for better control and is about improving the rate at which an agreed standard is achieved. It is therefore a process for reducing the spread of common cause variation so that all products meet agreed standards. This is illustrated in Figure 2.9. It is not about removing special cause variation, i.e. this requires the corrective action process.

This type of improvement is only about reducing variation about a mean value or closing the gap between actual performance and the target. This is improvement by better control and in some sectors is not regarded as improvement at all. In the automotive sector, continual improvement is implemented once manufacturing processes are capable and stable or product characteristics

are predictable and meet customer requirements.[12] The target remains static and the organization gets better and better until all output meets the target or falls between the acceptance limits.

When a process is stable the variation present is only due to random causes. There may still be unpredictable excursions beyond the target due to a change in the process but this is special cause variation. Investigating the symptoms of failure, determining the root cause and taking action to prevent recurrence can eliminate the special cause and reduce random causes. A typical quality improvement of this type might be to reduce the spread of variation in a parameter so that the average value coincides with the nominal value. Another example might be to reduce the defect rate from three sigma to six sigma. The changes that are needed to meet this objective might be simply changes in working practices or perhaps complex changes that demand a redesign of the process or a change in working conditions. These might be achieved using existing methods or technology but it may require innovation in management or technology to accomplish.

Can we keep on doing it right?

Would the answer be this?	No we can't because the supply of resource is unpredictable, the equipment is wearing out and we can't afford to replace it.
Or would it be this?	Yes we can because we have secured a continual supply of resources and have in place measures that will provide early warning of impending changes.

This question is about continuity or sustainability. It is not enough to do it right first time once, i.e. you have to keep on doing it right and this is where a further question helps to clarify the issue.

What affects our ability to maintain this performance?

It could be resources as in the example, but to maintain the status quo might mean innovative marketing in order to keep the flow of customer orders of the type that the process can handle. Regulations change, staff leave, emergencies do happen: Can you keep on doing it right under these conditions?

Are we doing it in the best way?

Would the answer be this?	We have always done it this way and if it isn't broke why fix it?
Or would it be this?	Yes we think so because we have compared our performance with the best in class and we are as good as they are.

One might argue that any target can be met providing we remove the constraints and throw lots of money at it. Although the targets may be achieved, the achievement may consume too much resource; time and materials may be

wasted – there may be a better way of doing it. By finding a better way you release resources to be used more productively and therefore bring about improvement through better utilization of resources.

Over 19 years since the introduction of ISO 9000, it is strange that more organizations did not question if there was a better way than writing all those procedures, filling in all those forms, insisting on all those signatures. However, ISO 9000 did not require these things – but there was more than one way of interpreting the requirement.

The search for a better way is often more effective when in the hands of those doing the job and you must therefore embrace the "leadership" and "involvement of people" principles in conjunction with continual improvement.

Is it the right thing to do?

Would the answer be this?	I don't know – we always measure customer satisfaction by the number of complaints.
Or would it be this?	Yes I believe it is because these targets relate very well to the organization's objectives.

Quality improvement in this context is accomplished by raising standards and is about setting a new level of performance, a new target that brings additional benefits for the stakeholders. These targets are performance targets for products, processes and the system. They are not targets established for the level of errors, such as nonconformities, scrap, and customer complaints. Such targets are not in fact targets at all, they are simply historical standards of performance.

One needs to question whether the targets are still valid so we ask, "How do we know this is the right thing to do?" These new targets have to be planned targets as exceeding targets sporadically is a symptom of out-of-control situations. Targets need to be derived from the organization's goals but as these change the targets may become disconnected. Targets that were once suitable are now obsolete – they are not the right things to do any longer. We need to ask, "Are these targets still relevant to the stakeholder needs?"

Functions are often measured by their performance against budget. We need to ask whether this is the right thing to do – does it lead to optimizing organizational performance? You may have been desensitized to the level of nonconformities or customer complaints – they have become the norm – is this the right level of performance to maintain or should there be an improvement programme to reach a much lower level of rejects.

New standards are created through a process that starts with an analysis of stakeholder needs and expectations followed by the identification of opportunities for change, then a feasibility stage, progressing through research and development to result in a new standard, proven for repeatable applications. Such standards result from innovations in technology, marketing and management. This is improvement by better understanding of stakeholder needs. A typical

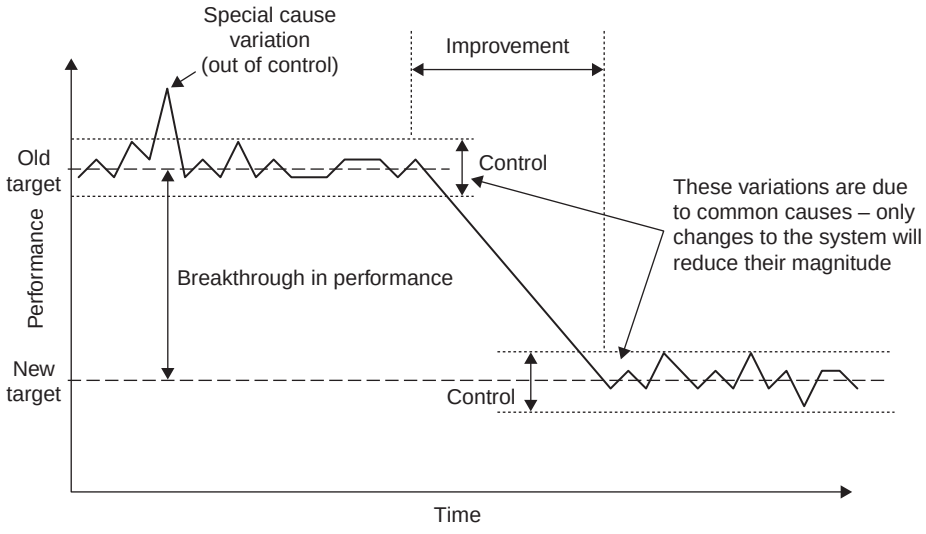

Figure 2.10 Breakthrough and control

quality improvement of this type might be to redesign a range of products to increase the achieved reliability from 1 failure every 5,000 hours to 1 failure every 100,000 hours. Another example might be to improve the efficiency of the service organization so as to reduce the guaranteed call-out time from the specified 36 to 12 hours or improve the throughput of a process from 1,000 to 10,000 components per week. Once again, the changes needed may be simple or complex and might be achieved using existing technology but it may require innovation in technology to accomplish.

The transition between where quality improvement stops and quality control begins is where the level has been set and the mechanisms are in place to keep quality on or above the set level. In simple terms, if quality improvement reduces quality costs from 25% of turnover to 10% of turnover, the objective of quality control is to prevent the quality costs rising above 10% of turnover. This is illustrated in Figure 2.10.

Improving quality by better control or raising standards can be accomplished by the following steps.

1. Determine the objective to be achieved, e.g. new markets, products or technologies, or new levels of organizational efficiency or managerial effectiveness, new national standards or government legislation. These provide the reasons for needing change.
2. Determine the policies needed for improvement, i.e. the broad guidelines to enable management to cause or stimulate the improvement.
3. Conduct a feasibility study. This should discover whether accomplishment of the objective is feasible and propose several strategies or conceptual solutions for consideration. If feasible, approval to proceed should be secured.

4. Produce plans for the improvement that specifies the means by which the objective will be achieved.
5. Organize the resources to implement the plan.
6. Carry out research, analysis and design to define a possible solution and credible alternatives.
7. Model and develop the best solution and carry out tests to prove it fulfils the objective.
8. Identify and overcome any resistance to the planned change in standards.
9. Implement the change, i.e. put new products into production and new services into operation.
10. Put in place the controls to hold the new level of performance.

This improvement process will require controls to keep improvement projects on course towards their objectives. The controls applied should be designed in the manner described previously.

Quality assurance (QA)

The ISO 9000 definition states that *quality assurance* (commonly abbreviated to QA) is part of quality management focused on providing confidence that quality requirements will be fulfilled. Both the customers and the managers have a need for quality assurance because they are not in a position to oversee operations for themselves. They need to place trust in the producing operations, thus avoiding constant intervention.

Customers and managers need:

1. Knowledge of what is to be supplied. (This may be gained from the sales literature, contract or agreement.)
2. Knowledge of how the product or service is intended to be supplied. (This may be gained from the supplier's proposal or offer.)
3. Knowledge that the declared intentions will satisfy customer requirements if met. (This may be gained from personal assessment or reliance on independent certifications.)
4. Knowledge that the declared intentions are actually being followed. (This may be gained by personal assessment or reliance on independent audits.)
5. Knowledge that the products and services meet the specified requirements. (This may be gained by personal assessment or reliance on independent audits.)

You may wonder why one needs to do (4) if you are doing (5) anyway! You can gain an assurance of quality by testing the product or service against prescribed standards to establish its capability to meet them. However, this only gives confidence in the specific product or service purchased and not in its continuity or consistency during subsequent supply. Another way is to assess the organization that supplies the products or services against prescribed standards

to establish its capability to produce products of a certain standard. This approach may provide assurance of continuity and consistency of supply.

Quality assurance activities do not control quality, they establish the extent to which quality will be, is being or has been controlled. All quality assurance activities are post-event activities and off-line and serve to build confidence in results, in claims, in predictions, etc. If a person tells you they will do a certain job for a certain price in a certain time, can you trust them or will they be late, overspent and over limits? The only way to find out is to gain confidence in their capability and that is what quality assurance activities are designed to do. Quite often, the means to provide the assurance need to be built into the process, such as creating records, documenting plans, documenting specifications, reporting reviews etc. Such documents and activities also serve to control quality as well as assure it. ISO 9001 provides a basis for obtaining an assurance of quality, if you are the customer, and a basis for controlling quality, if you are the supplier.

Quality assurance is often perceived as the means to prevent problems but this is not consistent with the definition in ISO 9000. In one case the misconception arises due to people limiting their perception of quality control to control after the event; not appreciating that you can control an outcome before the event by installing mechanisms to prevent failure, such as automation, error-proofing and failure prediction.

In another case, the misconception arises due to the label attached to the ISO 9000 series of standards. They are sometimes known as the quality assurance standards when in fact, as a family of standards, they are quality management system standards. The requirements within the standards do aim to prevent problems, and consequently the standard is associated with the term *quality assurance*. ISO 9001 is designed for use in assuring customers that suppliers have the capability of meeting their requirements. It is true that by installing a quality management system, you will gain an assurance of quality, but assurance comes about through knowledge of what will be, is being or has been done, rather than by doing something. Assurance is not an action but a result. It results from obtaining reliable information that testifies to the accuracy or validity of some event or product.

Labelling the prevention activities as quality assurance activities may have a negative effect, particularly if you have a Quality Assurance Department. It could send out signals that the aim of the Quality Assurance Department is to prevent things from happening! Such a label could unintentionally give the department an image of a law enforcement role.

Quality Assurance Departments are often formed to provide both customer and management with confidence that quality will be, is being and has been achieved. However, another way of looking on Quality Assurance Departments is as Corporate Quality Control. Instead of measuring the quality of products, they are measuring the quality of the business and by doing so are able to assure

management and customers of the quality of products and services. The following steps can obtain an assurance of quality:

1. Acquire the documents that declare the organization's plans for achieving quality.
2. Produce a plan that defines how an assurance of quality will be obtained, i.e. a quality assurance plan.
3. Organize the resources to implement the plans for quality assurance.
4. Establish whether the organization's proposed product or service possesses characteristics that will satisfy customer needs.
5. Assess operations, products and services of the organization and determine where and what the quality risks are.
6. Establish whether the organization's plans make adequate provision for the control, elimination or reduction of the identified risks.
7. Determine the extent to which the organization's plans are being implemented and risks contained.
8. Establish whether the product or service being supplied has the prescribed characteristics.

In judging the adequacy of provisions you will need to apply the relevant standards, legislation, codes of practice and other agreed measures for the type of operation, application and business. These activities are quality assurance activities and may be subdivided into design assurance, procurement assurance, manufacturing assurance, etc. Auditing, planning, analysis, inspection and test are some of the techniques that may be used.

Level of attention to quality

In the first section of the Introduction to ISO 9001 is a statement that might appear progressive but depending on how it is interpreted could be regressive. The statement is: "The adoption of a quality management system should be a strategic decision of an organization". What would top management be doing if they did this? Would they be:

a) Agreeing to implement the requirements of ISO 9001 and subject the organization to periodic third party audit as evidence of commitment to quality?
b) Agreeing to document the approach they take to the management of product quality and to subsequently do what they have documented?
c) Agreeing to manage the organization as a system of interconnected processes as a method of delivering stakeholder satisfaction?

It all comes down to their understanding of the word *quality* and this is what will determine the level of attention to quality.

Whilst the decision to make the *management of quality* a strategic issue will be an executive decision, the attention it is given at each level in the organization

Table 2.3 Attention levels

Organizational level	*Principle process focus*	*Basic team structure*	*Performance issue focus*	*Typical quality system focus*	*Ideal quality system focus*
Enterprise	Strategic	Cross-Business	Ownership	Market	Strategic
Business	Business	Cross-Functional	Customer	Administrative	Business Process
Operations	Work	Departmental	Process	Task Process	Work Process

will have a bearing on the degree of success attained. There are three primary organization levels: the *enterprise level*, the *business level* and the *operations level*.[13] Between each level there are barriers.

At the enterprise level, the executive management responds to the "voice" of ownership and is primarily concerned with profit, return on capital employed, market share etc. At the business level, the managers are concerned with products and services and so respond to the "voice" of the customer. At the operational level, the middle managers, supervisors, operators, etc. focus on processes that produce products and services and so respond to the "voice" of the processes carried out within their own function.

In reality, these levels overlap, particularly in small organizations. The Chief Executive Officer (CEO) of a small company will be involved at all three levels whereas in the large multinational, the CEO spends all of the time at the enterprise level, barely touching the business level, except when major deals with potential customers are being negotiated. Once the contract is won, the CEO of the multinational may confine his or her involvement to monitoring performance through metrics and goals.

Quality should be a strategic issue that involves the owners because it delivers fiscal performance. Low quality will cause fiscal performance ultimately to decline.

The typical focus for a quality management system is at the operations level. ISO 9000 is seen as an initiative for work process improvement. The documentation is often developed at the work process level and focused on functions. Much of the effort is focused on the processes within the functions rather than across the functions and only involves the business level at the customer interface, as illustrated in Table 2.3. For the application of quality management principles to be successful, quality has to be a strategic issue with every function of the organization embraced by the management system that is focused on satisfying the needs of all stakeholders.

Summary

In this chapter we have examined basic concepts and principles that underpin the body of knowledge of quality management. We have examined a plethora of terms, discarded the misconceptions and extracted the key messages in order to arrive at some universal principles that will help us discover the right things to do in achieving, sustaining and improving quality. In examining terms like quality control and quality assurance we have shown that these terms are not simply names for departments within an organization or processes but much broader concepts that apply to the management of any activity. We have paid particular attention to quality control because it is this more than any other topic that has been misunderstood. We have examined the concepts of standards, measurement and variation in some depth as these are at the heart of quality management. Finally we have shown that the achievement of quality is a strategic issue that requires a systems approach and this will be dealt with next.