

September 2011

UK position paper for the revision of ISO 9000

1 Introduction

This document has been drawn from a submission by the Chartered Quality Institute (CQI) for submission to ISO/TC 176, via the UK's mirror committee QS/1. It is intended as an input into any future revision of ISO 9000.

The implementation of quality management, as currently reflected in the ISO 9000 family of standards, has delivered outstanding results, but given the rapidly changing business environment that organizations face, is it delivering enough ?

Is our management thinking as currently expressed in ISO 9000 and the other standards in the ISO 9000 family still fit for purpose, and still achieving adequate results?

To address the changing demands we recommend that the content of ISO 9000 is reviewed and amended to ensure it continues to provide the foundations for the individual standards within the ISO 9000 family so that they remain consistent and compatible with each other e.g. through the promotion and application of the concepts, fundamentals and principles, and through the use of common terminology; as such it should also provide management with a compelling case for the adoption of quality management.

This paper provides a basis for discussion of changes in fundamental concepts, principles and vocabulary that are believed to be necessary to address these issues.

2 Fundamental concepts of quality management

2.1 The concept of organization purpose

Organizations are formed to fulfil a specific purpose and that purpose drives everything an organization does. For an organization to survive in the long term its purpose needs to be outwardly looking towards the external environment (2.1.2) in which it operates. No longer is business performance measured solely in terms of economic performance..

Organizations of any type need to take into account ecological and social performance in addition to financial performance. In all other organizations economics is a restraint to what the organization and its managers can do.

Profit or surplus is important as a resource, a measure of success and must be sufficient to cover the risks but when perceived as a primary purpose of an organization it encourages managers to look inwardly at financial returns instead of outwardly at the contribution an organization makes to society which is the ultimate judge of its performance. It is therefore vital that the true purpose of the organization is clearly communicated to all those with whom it is involved. Typically this may involve the development of a long term purpose (e.g. Vision and Mission, policies, and improvement objectives) as well as short term performance objectives.

2.2 The concept of external environment

An organization is bounded by its external environment and can adapt to that environment or seek to shape it to survive and achieve its aims. It may deliberately influence but cannot control all parts of that external environment or simply react to changes but must understand their influence on itself for the organisation to survive and can choose which parts it works with and how it responds to change.

Note ISO 9004 defines the organization's environment as:

3.2

organization's environment

“combination of internal and external factors and conditions that can affect the achievement of an organization's objectives and its behaviour towards its interested parties”

2.3 The concept of a management system

An organization is a complex and dynamic entity that uses a system of management for accomplishing its purpose (2.1) and delivering its desired outcomes. This management system covers the whole organisation and everything it does. It comprises the structure, processes and resources needed to establish an organization's policies and objectives and to implement the policies and achieve those objectives.

An organization's capability to deliver desired outcomes depends on its leadership's ability to align its mission, vision, values and culture with the strategies, policies, processes and resources it employs to achieve them.

Organizations that sustain their capability:

- a) are adaptive to their external environment;
- b) continually enhance their capability to change/adapt;
- c) develop collective as well as individual learning;
- d) use the results of learning to achieve better results.

An organization's outcomes can be intended or unintended, and anticipating their possible impact is an essential element in managing performance. Desired outcomes for all of the organisation's interested parties are more likely to be achieved if its objectives and priorities are consistent with those desired outcomes.

Successful performance depends on identifying and managing risks to an organization's capability to deliver planned outcomes consistently. This system can be examined from the perspective of particular objectives such as financial, quality, social responsibility, environment, health and safety etc. This can result in these different perspectives being labelled financial management system, quality management system, environmental management system etc. In reality these subsystems are parts of the whole system each of which can affect its behaviour or its properties but which cannot operate independently.

Although critical components need to be documented for effective communication, every aspect of the management system can never be fully documented. Any description of a system is at best a model or a particular perspective of reality and in some respects will always be wrong but will often be useful.

2.4 The importance of interested parties

Organizations need to attract, capture and retain the support of those organizations and individuals they depend upon for their success. These are an organization's interested parties and include customers, investors, employees, suppliers and society. Each has a distinct role in influencing the manner in which an organization fulfils its mission so that managing the expectations of these groups of interested parties becomes a critical success factor in any organization. The organisation has no control or choice over some interested parties, such as society and its political impacts but does have a choice over who its employees, customers and suppliers are and what outcomes are delivered to them.

Customers impose the primary demands on the organization's goods and services. The needs of the other interested parties place constraints upon an organization's strategy for meeting those demands.

Without customers there is no revenue and without revenue there is no business or community to serve. Customers are therefore the most important interested party but in meeting their demands, organizations are obligated to operate in such a manner that satisfies the legitimate needs and expectations² of the other interested parties although they do have a choice as to which customers to work with. Consequently interested party management is a key aspect in defining objectives.

2.5 The concept of quality

Quality is defined as the "degree to which a set of inherent characteristics fulfils requirements". The degree to which interested party expectations are met defines the quality of an organization's outputs which include e.g. goods and services, dividends, information and employee satisfaction.

Quality is perceived in several ways:

- a) satisfying interested party needs and expectations where the gap is the degree of satisfaction regardless of the stipulated requirements;
- b) conformity with customer requirements where the gap is the degree of conformity regardless of the significance of any nonconformities;
- c) freedom from deficiencies where the gap is the level of deficiency regardless of significance.

There are many reasons for paying attention to quality, including:

- a) maintaining competitiveness
- b) maintaining reputation and brand equity
- c) managing innovation
- d) minimising waste and reducing internal costs
- e) achieving sustained success

Consequently quality needs to be the first priority in any organization. Companies that put 'profits first' have found themselves losing market position because of the inferior quality and price competitiveness of their goods and services. When quality is the first priority there are no boundaries. With every product there is a service e.g. delivery or after sales, and with every service there is product e.g. information or materials and a process of delivering it. It would be inequitable to pursue a quality first approach with products and a different approach with services and processes, e.g. putting quality first in the supply of electricity but not in its generation, putting quality first in the supply of automobiles but not in their production, delivery and servicing.

It has to be recognised that putting customers first is not the same as putting quality first because organizations can control the quality of its outputs but not its customers. Customers often think short term, don't know what they need and often don't care about the impact of their demands on other interested parties.

The quality of an organization's goods and services is judged by the ability of their inherent characteristics to not only satisfy particular customers but also to capture a sustainable market."

2.6 The concept of quality management

2.6.1 The purpose of quality management

For an organization to fulfil its mission (or purpose) and achieve its strategic objectives its activities have to be managed towards these objectives if its mission is to be fulfilled effectively.

An organization's strategic objectives are derived from understanding and prioritising the mix of interested party needs relative to its mission and these will include objectives for marketing, innovation, human, financial and physical resources together with financial, social and ecological performance including ethics. Among these objectives has to be the objective of delivering outputs of a quality that satisfy interested party's expectations as economically as is practical whatever the chosen market, product and associated resources. The purpose of quality management is therefore to provide an organization with the capability of delivering the required outputs and managing that capability in a way that produces the desired outcomes for the interested parties.

2.6.2 Quality as first the priority

Organizations that have made quality their first priority have demonstrated a significant improvement in the quality of their goods and services and as a result improved their safety and reliability. This has led over time to a substantial increase in productivity and price competitiveness leading to increase profit and market share. Quality management is therefore of strategic importance in every organization seeking to produce high quality goods and services, at low cost and high productivity which benefit society and the ecology thus seeking sustained success. Consequently organizations need to set strategic quality objectives that are derived from the needs and expectations of its interested parties and develop strategies and structures for achieving those objectives.

2.6.3 Quality planning

For quality to be the first priority of an organization it follows that this needs to be translated into objectives and plans for achieving those objectives. This has evolved as the concept of quality planning where effort is focussed on understanding customer needs, developing and validating product features that respond to those needs and developing and validating processes capable of producing those product features.

2.6.4 Quality control

To consistently achieve quality it is necessary to apply appropriate control to minimise uncertainty in the achievement of desired outputs. As variation can be detrimental to an organization's performance the concept of quality control has evolved to set standards of performance and detect and remove undesirable variation in order to prevent change in accepted standards. If performance becomes predictable, organizations can plan the future with confidence that the plans will be carried out.

The detection and removal of variation may be effected:

before an output is produced by such means that anticipates potential problems and institutes techniques that eliminate particular modes of variation through product and process design;
during the production of an output by such means that detects and removes variation as it occurs so that subsequent processing may continue;
after an output has been produced by such means that rectify problems before release of the output.

2.6.5 Quality improvement

Organizations not only need to maintain standards of performance but also look for better ways of achieving their objectives and raise standards of performance in order to sustain success as new threats and opportunities emerge in their operating environment.

The concept of quality improvement has evolved for improving performance by better control of quality, by better utilization of resources and better alignment of objectives with those of the organization's interested parties.

When undertaking improvement, the performance of each variable can be improved independently until the slack among them is used up. Then the perceived set of independent variables changes to a formidable set of interdependent variables. Improvement in one variable would come only at the expense of the others.

Corrective action is not improvement, it is part of quality control and it simply restores performance to where it should have been.

2.6.6 Quality assurance

To be able to buy with confidence customers need to have trust in a particular product from a particular organization and this trust can only be obtained through an organization developing its reputation for its capability to control the quality of its goods and services and when necessary being prepared to demonstrate this capability to others.

In addition, top management need safeguards against inadvertent deterioration in standards that may arise through changes in personnel, reorganizations and the unforeseen consequences of planned changes and localised initiatives.

For top management to have confidence in the integrity of the management system, and for customers to have trust in the products of an organization, there needs to be a degree of independent verification of performance that is proportional to the significance of failure.

The concept of quality assurance has evolved to provide to those concerned, when necessary, the evidence needed to establish confidence that quality is being managed effectively and desired standards of performance maintained at all levels in the organization.

2.7 People, Processes and Resources

Achieving the desired level of quality depends upon an organization possessing competent people, capable processes and adequate resources. Quality cannot be inspected into goods and services, it has to be built-in through robust product and process design, and

faithful implementation of those designs by people possessing the necessary competences.

2.7.1 People

An organization's performance emerges from how people behave, rather than what people document or say they do and this depends upon the degree to which they are involved in decisions that affect their work. All people are different and the performance of anyone is largely governed by the system in which they work. Empowerment can create conditions in which people are motivated because it offers a way of obtaining higher level of performance without strict supervision.

The more complex an organization the more numerous the interrelationships and more resilient the organization will be to fluctuations in the performance of individuals. Consequently when individuals fail to do their job, there will be others who will step in to support them and fill the void. However, sustained success will only be assured if harmonious relationships have been nurtured and this depends on continual good leadership.

It is also important for sustained success in an organization not only that its people are competent and understand their role in the achievement of quality, but that there needs to be a combination of competencies within the organization that collectively address issues such as:

- a) an appreciation of systems thinking: understanding the nature and properties of systems and how the interaction of parts produce the organization's outcomes and not the individual parts themselves;
- b) knowledge of variation: the range and causes of variation in quality, and use of statistical sampling in measurements;
- c) theory of knowledge: the concepts explaining knowledge and the limits of what can be known;
- d) knowledge of psychology: concepts of human nature.

Note also the QMP on leadership.

2.7.2 Processes

All work is accomplished by a process and a process can be designed to produce outputs with any desired features or characteristics by altering the variables of inputs, activities, resources, influences and controls. It follows therefore that by designing and managing processes effectively they will consistently and continually produce outputs of the desired quality.

Strategic objectives are generally achieved through a network of processes that span several functions or departments within an organization. These processes can be classified into three groups:

- a) those which create and satisfy customer demands e.g. marketing, product development, production, service delivery, sales and after sales service;
- b) those which manage the enterprise e.g. strategic planning, organization development, management system design, performance evaluation and improvement;
- c) those which supply all processes with resources e.g. human resources, materials, facilities management, IT, finance and maintenance.

Tactical objectives are derived from the strategic objectives and achieved through processes executed primarily by a single function with a low level of support from other functions. These have a narrow scope often limited to a single task or few steps e.g. producing a plan, assigning tasks, making a component, checking conformity, correcting errors and producing a report but they are connected with other micro-processes to form a network of processes that constitute a macro-process serving a specific strategic objective.

Effectively managed processes are those which are designed to achieve specific objectives, are subject to continual monitoring, review and improvement consistent with those objectives as illustrated in Figure 1.

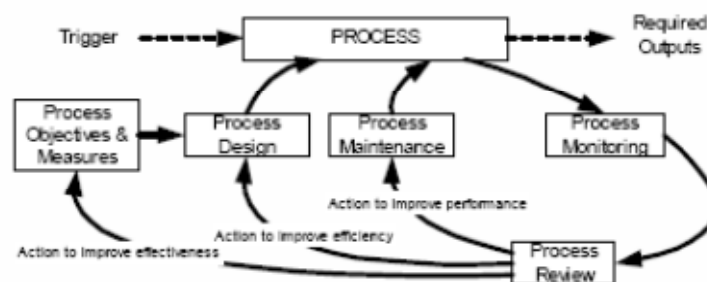


Figure 1 A managed process (How consistent results are achieved)

Process objectives relate to the outputs the process is designed to produce e.g. an order that the organization is capable of fulfilling, a design that reflects customer needs, a product that conforms to the specification or a delivery that exceeds customer expectations.

Process measures are characteristics by which achievement of the process objectives is judged e.g. on time delivery, yield, injuries, emissions and downtime. These measures are used in process monitoring to determine the behaviour, performance and efficiency of the process.

Process reviews assess the results of process monitoring to determine whether the process needs to be adjusted to improve its performance through better control, improve its efficiency through better utilization of resources or improve its effectiveness through better alignment of the process objectives and measures with the needs and expectations of the organization's interested parties.

Process maintenance plans and carries out the agreed process changes to bring about better control. The relationship amongst the key elements that need to be managed to produce outputs of the required quality is illustrated in Figure 2.

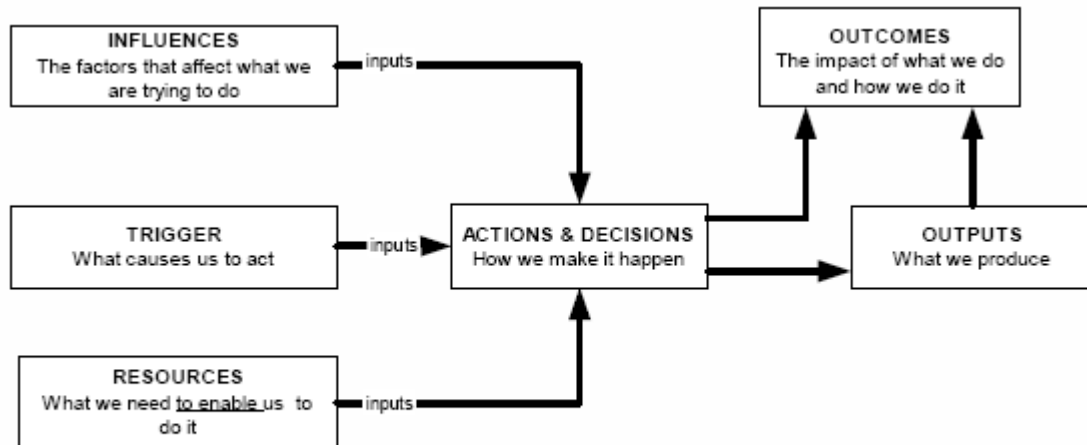


Figure 2 An operating process (How work gets done)

Although it is customary to think of a process as transforming inputs into outputs as illustrated in Figure 1, not all inputs will be transformed by the process.

The effectiveness and capability of, and the risks within, an organization can best be determined by (i) measuring the results of past activities and (ii) analysing indicators that help to predict future performance.

Continuing success depends on achieving an appropriate balance between conformity and the reduction of variation on the one hand, and innovation, responsiveness and improvement on the other.

2.7.3 Resources

For a process to deliver the desired outputs it has to be resourced and the requirement for these resources built into the process design. When the process is triggered the necessary resources have to be available for the process to maintain its capability. Consequently, the planning, acquisition, deployment and maintenance of resources of the requisite quality and quantity are essential for processes to maintain their capability. It is also essential that obsolete or redundant resources and resources of unsatisfactory quality are disposed of in ways that satisfy the expectations of all interested parties.

3 Principles

3.1 Introduction to the quality management principles

3.1.1 Proposition

This section defines the principles and application criteria which characterise effective quality management. Principles are needed to help people determine the right things to do given the situation they are seeking to manage. This concept is illustrated in Figure 3. The

more prescription there is, the more people become immersed in detail and lose sight of their objectives therefore principles should help people understand why they should follow the prescription. Application criteria are needed to ensure effective application of the principles. Applying the principles defined in this section will enable people to maintain a clear focus on an organization's objectives.

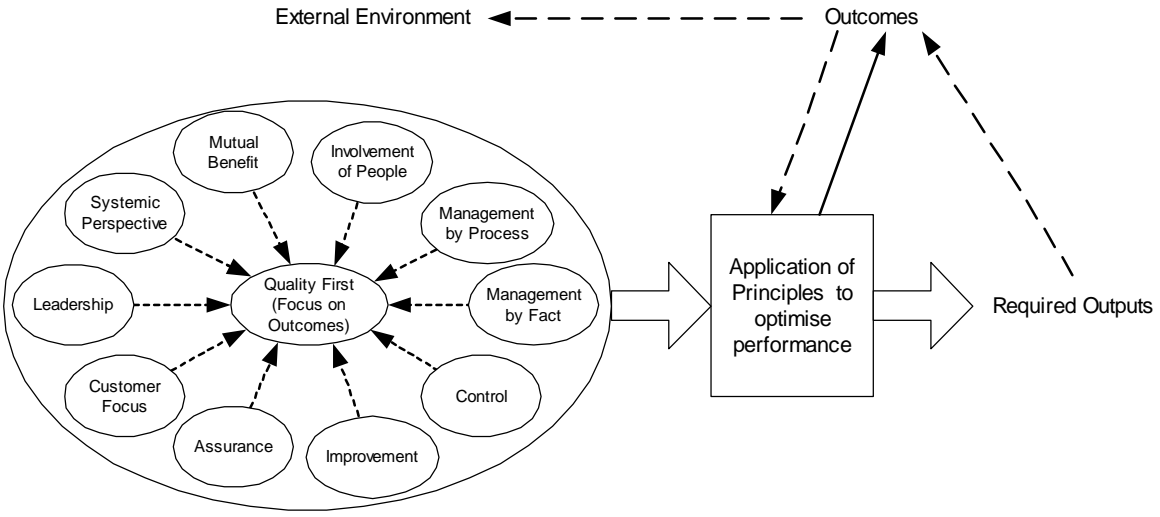


Figure 3. Applying the quality management principles to achieve an organization's objectives

These principles are derived from the fundamental concepts as shown in Table 1.

Table 1 Relationship between concepts and principles

Fundamental concept	Associated principles
Organization purpose	Leadership
External environment	Systemic perspective
Management system	Management by process Systemic perspective Customer focus Leadership
Importance of interested parties	Mutually beneficial relationships Customer focus
Importance of quality	Quality first
Quality management	Leadership Assurance Control Improvement Management by fact
Achieving quality through effectively managed people, processes and resources	Involvement of people Leadership Systemic perspective Management by process
Role of standards	Customer focus Assurance

Fundamental concept	Associated principles
	Control Mutually beneficial relationships

3.1.2 Justification

The introduction to the quality management principles in ISO 9000:2005 needs to provide a stronger message as to the role of principles. The current wording implies they are only used by top management when in reality these principles should be understood and used by everyone in an organisation.

3.2 Customer focus

3.2.1 Proposition

Organizations depend on their customers and therefore need to understand current and future customer needs and expectations and strive to satisfy those needs and expectations.

- a) An organization applying the customer focus principle will be one in which people:
- b) listen to their customers and understand the needs and expectations of those customers the organization chooses to work with and are sensitive to their preferences;
- c) meet customer requirements in a way that meet the needs and expectations of all other interested parties;
- d) communicate these needs and expectations throughout an organization;
- e) acquire the knowledge, skills and resources required to satisfy an organization's customers;
- f) measure customer satisfaction and act on results;
- g) understand and pro-actively manage customer relationships especially where their expectations might not be met;
- h) relate their behaviour, actions and objectives directly to customer needs and expectations;
- i) act on the results of customer satisfaction measurements and improve their performance.

3.2.2 Justification

The customer focus principle should be expressed as a truth not as a recommendation which inclusion of the word should implies. Exceeding customer requirements might be exemplary but exceeding customer expectations is only prudent when those expectations have been set by a less than exemplary performance record, e.g. trains are frequently late, therefore customer's expectation is that the next train will be late. Exceeding an expectation in such a case is simply achieving the original target.

3.3 Quality first

3.3.1 Proposition

To ensure productivity, safety, efficiency and effectiveness the quality of work must be the number one priority at all levels.

An organization applying the quality first principle will be one in which people:

- a) mean and do what they say when they say they will do it;
- b) can be trusted to supply the required outputs of the required quality on time;
- c) find the best value solutions that fulfil the requirements;
- d) are authorised to stop a process that is going out of control;
- e) don't compromise on the quality of work in return for short term gain;
- f) act ethically and with transparency in what they do to build trust;
- g) help colleagues to fulfil process objectives;
- h) are aware of what they do to others and Society generally and manage any risk of the impact of their outcomes before they become a reality.

3.3.2 Justification

The notion that quality be the first priority emerged from Japan's rise to dominance as they won competitive advantage over the West after WWII. Ishikawa wrote *"Japanese companies have been guided by the principle of "quality first" in accepting and practicing total quality control"* He continued... *In contrast American managers have taken the path of seeking short range goals. They have adhered to the principle of "profit first" and in the process lost to Japan in competition"*

The justification for including "quality first" is made in Section 2.6.2 and to add to this, it has to be recognised that putting customers first is not the same as putting quality first because customers often don't know what they need and often don't care about the impact of their demands on other stakeholders. The quote from Ishikawa should be sufficient justification but The Kings Fund also emphasises putting quality first in a book "Putting quality first in the boardroom" Making quality a global priority is the ASQ Vision.

3.4 Leadership

3.4.1 Proposition

Leaders establish unity of purpose and direction for an organization. They create and maintain the internal environment in which people are engaged in achieving the organization's objectives.

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

- a) establish and communicate a consistently clear vision of the organization's future;
- b) establish shared values and ethical role models at all levels of the organization;
- c) recruit people whose values and behaviour align with those of the organization;
- d) are proactive and lead by example by behaving in a way that is consistent with the organisation's, mission, vision and values;
- e) listen to their people and understand the needs of their team and help to meet them;
- f) understand and respond effectively to changes in the external environment;
- g) embrace discontinuous change and assist evolution and breakthrough change;
- h) extract high levels of performance from themselves and a similar level of performance from those they work with;
- i) consider the needs of all interested parties;
- j) build trust, eliminate fear and act ethically;
- k) provide people with the required resources and freedom to act with responsibility and accountability;
- l) promote open and honest communication;
- m) educate, train and coach people;
- n) set challenging objectives including measures and targets aligned to an organization's mission and vision; (in this context objectives are the results to be achieved, measures are the characteristics by which performance is judged and targets are the level of performance to be achieved);
- o) communicate and implement a strategy to achieve these objectives;
- p) use performance measures that encourage behaviour consistent with these objectives.

3.4.2 Justification

The leadership principle should be expressed as a truth not as a recommendation which inclusion of the word should implies. The principle would be enhanced by including application criteria similar but more concise than the guidance provided in ISO 9004.

3.5 *Involvement of people*

3.5.1 Proposition

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

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

- a) accept ownership and responsibility to solve problems;
- b) actively seek opportunities to make improvements;
- c) actively seek opportunities to enhance their competencies, knowledge and experience;
- d) freely share knowledge and experience in teams and groups;
- e) focus on the creation of value for customers;
- f) listen to what the leaders want for the organization and are innovative and creative in furthering the organization's objectives;
- g) represent their organization more positively to customers, local communities and society at large;
- h) derive satisfaction from their work;
- i) are enthusiastic and proud to be part of an organization;
- j) are supported in their career development and personal issues.

3.5.2 Justification

The principle would be enhanced by including application criteria similar but more concise than the guidance provided in the QMP Brochure.

3.6 *Management by process*

3.6.1 Proposition

Objectives can be achieved more effectively and efficiently at any level if the work to achieve them is managed across an organization regardless of the functions or levels of those involved in executing the work.

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

- a) are aware of the chain of processes that deliver an organization's outputs, in which processes they work and how their work contributes to the quality of these outputs;
- b) know the objectives they have to achieve and the process that will enable them to achieve them;
- c) know what measures will indicate whether the objectives have been achieved;
- d) have clear responsibility, authority and accountability for achieving the objectives;
- e) perform only those activities that are necessary to achieve these objectives;

- f) assess risks to success and put in place measures that eliminate, reduce or control these risks;
- g) know what resources, behaviours, information and competences are required to achieve the objectives;
- h) know whether a process is achieving its objectives as measured;
- i) find better ways of achieving the process objectives and of improving process efficiency;
- j) regularly confirm that the process objectives including the measures and targets remain relevant to the needs of an organization.

3.6.2 Justification

The difference between systems and processes is unclear and contradictory when the narratives on these topics are compared across ISO 9000, ISO 9001 and ISO 9004.

The principle would be enhanced by including application criteria similar but more concise than the guidance provided in the QMP Brochure.

3.7 Systemic perspective

3.7.1 Proposition

The component parts of a system can best be understood in the context of relationships with each other and with other systems, rather than in isolation.

An organization in which people take a systemic perspective will be one in which they:

- a) seek to understand the big picture;
- b) observe how elements within systems change over time, generating patterns and trends;
- c) identify the circular nature of complex cause and effect relationships;
- d) surface and test assumptions;
- e) consider how mental models affect current reality and the future;
- f) find where unintended consequences emerge;
- g) uses understanding of system structure to identify possible leverage actions;
- h) recognize the impact of time delays when exploring cause and effect relationships;
- i) recognize that a system's structure generates its behaviour;
- j) changes perspectives to increase understanding;

- k) consider an issue fully and resists the urge to come to a quick conclusion;
- l) considers both short and long-term consequences of actions;
- m) checks results and changes actions if needed.

3.7.2 Justification

There are at least four labels we could give to this principle Systems approach, Systems focus, Systems thinking and Systemic perspective. An approach is a method of tackling an issue. It is not a principle. Systems focus is a way of thinking but not a principle, whereas taking a particular perspective when carrying out actions or decisions is about applying a principle.

The difference between systems and processes is unclear and contradictory when the narratives on these topics are compared across ISO 9000, ISO 9001 and ISO 9004.

The Systems approach principle embodies systems thinking but does not capture the properties that characterise systems. Neither does it align with the section 2.3 Quality management systems approach which does not mention process interactions and which is more descriptive of the process approach than a systems approach.

The principle would be enhanced by including application criteria similar but more concise than the guidance provided in the QMP Brochure.

3.8 Improvement

3.8.1 Proposition

The pursuit of improvement strategies is essential for organizations to maintain and change their performance over the long term.

The improvement process consists of a series of universal steps as follows:

- a) study performance to identify and prove the need for improvement;
- b) determine the objective of the improvement;
- c) conduct a feasibility study to establish that improvement is feasible within prevailing economic constraints;
- d) define the means by which the objective will be achieved;
- e) organize the resources to implement the improvement plan;
- f) carry out research, analysis and design to produce a solution and credible alternatives;
- g) model and develop the best solution and verify it fulfils the objective of the improvement;

- h) identify and overcome any resistance to change;
- i) implement the change in all applicable areas;
- j) put in place controls to hold the new level of performance.

This sequence of steps can be applied at any level at which objectives are specified. It may also be applied to the development of new products and processes and to improvements in product features and processes for producing those product features.

An organization applying the improvement principle will be one in which people:

- a) challenge the status quo without fear;
- b) continually look for ways in which the quality of goods, services, processes and systems can be improved for the benefit of an organization's interested parties;
- c) apply the basic improvement concepts of incremental, breakthrough and transformational improvement as appropriate;
- d) use periodic assessments against established criteria of excellence to identify areas for potential improvement;
- e) improve the efficiency and effectiveness of processes using relevant problem solving and improvement techniques;
- f) are educated and trained in the methods and tools of improvement;
- g) understand that improvement arises from doing things differently not by doing things in the same way;
- h) understand that desired outcomes arise from directing effort towards doing the right things and not only at doing things right;
- i) understand that improvement which is directed at improving the parts taken separately may not improve the overall performance of the system.

3.8.2 Justification

While the principle of improvement is addressed in ISO 9000 it is limited to continual improvement and not other types of improvement that are used for organizations to sustain success. Changes to the continual improvement principle are therefore needed.

The improvement principle should be expressed as a truth not as a recommendation which inclusion of the word should implies and would be enhanced by including application criteria similar but more concise than the guidance provided in the QMP Brochure.

3.9 Management by fact

3.9.1 Proposition

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

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

- a) define performance measures that relate to the quality characteristics required for the process, or product to be measured;
- b) take measurements and collect data and information relevant to the product, or process objective;
- c) ensure that the data and information are sufficiently accurate, reliable and accessible;
- d) analyse the data and information using valid methods;
- e) understand the value of appropriate statistical techniques;
- f) understand that past performance is not necessarily indicative of future performance;
- g) use cost of quality data to inform decision makers of the economical significance of results;
- h) make decisions and take action based on the results of logical analysis balanced with experience and intuition.

3.9.2 Justification

An approach is a method of tackling an issue. It is not a principle and therefore a title more consistent with a principle would be better.

The principle would be enhanced by including application criteria similar but more concise than the guidance provided in the QMP Brochure.

3.10 Mutually beneficial relationships

3.10.1 Proposition

Every organization depends on the support of its investors, customers, employees, suppliers and the community to achieve its strategic objectives and needs to foster a mutually beneficial relationship in exchange for the risks they bear.

An organization applying the mutual beneficial relationship principle will be one in which people:

- a) have mutual respect for the needs of others regardless of their role in supporting an organization;

- b) identify and select key suppliers on the basis of their ability to meet requirements without compromising quality;
- c) achieve quality requirements without compromising health, safety and the natural environment;
- d) establish external relationships that balance short-term gains with long-term considerations for an organization and society at large;
- e) create clear and open internal and external communications;
- f) initiate joint development and improvement of goods, services and processes;
- g) jointly establish clear understanding of stakeholder needs;
- h) share information and future plans;
- i) recognize supplier improvements and achievements;
- j) engage with each of the stakeholders as appropriate when assessing the system's performance.

3.10.2 Justification

The current principle of mutually beneficial relationships is limited to suppliers but there are other interested parties upon which an organization depends to accomplish its goals and thus the principle appears to be written only for assurance purposes and not quality management purposes.

The principle would be enhanced by including application criteria similar but more concise than the guidance provided in the QMP Brochure.

3.11 Assurance

3.11.1 Proposition

The need for confidence in the integrity of the provisions made to create and supply goods and services increases in proportion to the complexity of organizations and their goods and services.

The assurance process consists of a series of universal steps as follows:

- a) determine how objectives have been derived and their achievement planned;
- b) review the plans to verify that, if followed, they will result in interested party satisfaction;
- c) plan and conduct audits to verify the plans are being followed and the objectives met.
- d) An organization applying the assurance principle will be one in which managers :

- e) understand the requirements an organization is under obligation to satisfy;
- f) understand the complexity of the plans for meeting these requirements and confirm that these plans, if followed, will deliver outputs that meet the requirements;
- g) decide the level of assurance required on the basis of the risks that will be encountered in implementing these plans;
- h) gather objective evidence that plans are being followed;
- i) gather objective evidence that requirements are being met.

3.11.2 Justification

Both customers and managers have a need for an assurance of quality 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. These needs are expressed by the internal audit requirement in ISO 9001 and the use of ISO 9001 by internal and external parties, to assess an organization's ability to meet customer, statutory and regulatory requirements. None of these provisions can be derived from the existing principles and therefore there is an omission.

3.12 Control

3.12.1 Proposition

To attain and maintain standards for performance, work needs to be under control and this only arises when those with responsibility for the work are aware of those standards and are able to regulate the variables that cause variation in their performance.

The control process consists of a series of universal steps abbreviated as follows:

- a) determine the quality objectives for the characteristics to be controlled in terms of the units of measure and target values;
- b) establish sensing devices to measure the characteristics in terms of the unit of measure;
- c) conduct measurement and compare actual performance with the objectives;
- d) act on the difference.

This sequence of steps can be applied at any level at which objectives are specified.

An organization applying the control principle will be one in which people:

- a) are not held accountable for results over which they have no control;
- b) decide what needs to be controlled (the objective) on the basis of what is important for an organization to meet the needs of its interested parties;

- c) develop or choose appropriate units of measure for the parameters to be controlled;
- d) establish or choose a standard level of performance or target value that is consistent with the organization's objectives and communicate such standards to those concerned before work commences;
- e) create or choose capable sensory devices for measuring characteristics either before, during or after those characteristics have been produced depending on their significance;
- f) utilize the necessary resources for carrying out the required measurements;
- g) undertake the planned measurements and compare potential or actual performance with the target at a stage in the process where correction of any potential or actual variation detected is economic;
- h) ensure the results of measurement are transmitted to the appropriate levels of the organization in a form suitable for prompt decisions to be taken on the action needed;
- i) verify the validity of the reported results, evaluate their economic and statistical significance and discover the factual cause of variation from the standard before action is taken;
- j) evaluate alternative courses of action and ensure that decisions are taken in a timely manner by the people who are accountable for the results of the particular process under control;
- k) are motivated to take the action that has been agreed to bring performance in line with the standard in a timely manner;
- l) are motivated to verify that the action taken has had the desired effect and performance has returned to normal.

3.12.2 Justification

An axiom of management is that all work is either directed at maintaining standards or changing them and there is no existing principle that is focused on control even though there are many requirements in ISO 9001 that owe their origin to a principle of control.

3.13 Model of a process-based management system

3.13.1 Proposition

The diagram of a process based quality management system in ISO 9000, ISO 9001 and ISO 9004 is seriously flawed for several reasons and should be removed.

3.13.2 Justification

- a) an organization is too complex for it to be modelled in such a way;

- b) the elements within the ellipse imply processes but in fact they are simply the headings of sections 5, 6, 7 & 8 of the standard. some of the requirements are deliberately placed in section 8 because the only section where exclusions are permitted is section 7; hence product measurement and nonconformity control, which should be part of product realization, are included in section 8 and not section 7;
- c) management responsibility is not a process but a series of obligations;
- d) separating measurement, analysis and improvement implies that the output from product realization is not measured because product measurement is addressed in section 8 of the standard not section 7;
- e) the continual improvement element that sits outside the ellipse implies it's outside the system when it is already addressed by the measurement analysis and improvement element and indeed the requirements of section 8;
- f) the diagram omits other interested parties upon which the delivery of outputs depend such as suppliers, employees and investors;
- g) there is no indication of the influence of the business environment mentioned in clause 0.1 of the standard;
- h) only a very limited number of "information flows" and "value-adding activities" are shown;
- i) the use of the terms "customer" and "product" is compromised by conflicting definitions in section 3 of ISO 9000.

3.14 Promoting application of the concepts and principles of quality management

3.14.1 Proposition

ISO 9000 should be invoked in clause 5.1 of ISO 9001 requiring the quality policy, quality objectives and quality management system to be consistent with the fundamental concepts and principles defined in ISO 9000 so that it makes ISO 9000 part of the assessment criteria.

3.14.2 Justification

Only section 3 of ISO 9000 is invoked as a normative vocabulary standard in ISO 9001. Section 2 of ISO 9000 and ISO 9004 are normative guidance standards and thus are not used as assessment criteria when using ISO 9001, which means that the concepts and principles of quality management are being ignored by users and consequently being misguided as to intent.

ISO 9001 has the greatest usage of any standard in the family primarily because of its use for certification purposes. Ideally ISO 9000 should be used equally as well because the

normative reference in ISO 9001 means that ISO 9000 is indispensable for the application of this document.

ISO 9000 contains the terms and definitions for concepts used in the ISO 9000 family of standards but in our survey 39% said they don't use ISO 9000. An even more disturbing finding is that 50% of auditors among the respondents don't use ISO 9000 in spite of a statement in ISO 9001 that ISO 9000 is indispensable for the application of this document even though 94% of the auditors in our survey claim to have read ISO 9000 and rather less (73%) ISO 9004. In so far as the terms and definitions in ISO 9000 are normatively referenced in ISO 9001 (and all the ISO 9000 family of standards) there is a serious need to get these terms and definitions more widely known and used by all users of the ISO 9000 family of standards. Achieving this objective would have the equally beneficial result that the guiding principles in ISO 9000 section 2 would become equally widely known and understood.

In our survey 39% of those who use ISO 9001 say they don't use ISO 9000 even though 88% had read it and 62% say they don't use ISO 9004 but the same percentage have read it.

4 Vocabulary

4.1 Adopting a more user-friendly vocabulary

4.1.1 Proposition

So as to make the distinction between levels, more common business terms should be introduced into ISO 9000 vocabulary e.g, mission, vision, strategy, business process, work process, business objectives, and process objectives. This could be done by introducing within the associated notes of a definition examples of the terms used in the field of application of the term that is defined.

4.1.2 Justification

ISO 9000:2000 was prepared to provide terms only for the 2000 series of documents whereas it should be a general vocabulary on quality management

Despite attempts to express the requirements of ISO 9001 in plain English, in our survey 24% of the suggestions for improvement were concerned with the way requirements and guidelines were expressed.

In many cases specific labels are introduced into the field of quality management by ISO 9000 and ISO 9001 which has often led to disintegration of an organization's management system Terms such as quality manual, quality policy, quality objectives, management review, management representative and preventive action have often resulted in separate documents and activities carrying these labels instead of existing documents and activities being perceived as capable of meeting the requirement with minor adjustment.

Another issue is that general terms with broad field of application are used when a narrower field of application is required. e.g:

- a) the term product can mean any result of a process from a Strategic or Corporate level down to the result of performing a single task of a procedure;
- b) the term objective can mean any result to be achieved from the strategic to the tactical level;
- c) the term process can be a means of producing any output from strategic to the tactical level;
- d) both the terms “customer” and “product” are used in contradictory or confusing ways e.g.; Internal customer” v “customer oriented processes / “product” = “the result of a process” v “product realisation”.

So as to make the distinction between levels, more common business terms should be introduced into ISO 9000 vocabulary e.g, mission, vision, strategy, business process, work process, business objectives, and process objectives.

4.2 Maintaining on-line vocabulary database

4.2.1 Proposition

An up to date public vocabulary database should be maintained on the ISO Web site that is used by standards writers and users.

4.2.2 Justification

The terms and definitions of ISO standards are already available in the ISO Concept Database <https://cdb.iso.org/cdb/search.action> but its existence is not widely known to users outside ISO Committees.

Given that the vocabulary in ISO 9000 tends to lag behind the other standards and the omission of terms from ISO 9001 suggests that if the revisions cycles cannot be brought in alignment and the fundamental terms included in ISO 9001, there is a compelling case for maintaining the vocabulary in a database that is accessible to standards writers and users from the ISO Web site so that it will remain up to date.

4.3 Definition of customer

4.3.1 Proposition

The term customer should be defined as follows and the examples and notes removed:

“an organisation or person that receives, purchases or uses a product (qv) from the Organisation”.

4.3.2 Justification

There is a need to avoid the contradiction with “internal customers”, “customer oriented processes”, “customer requirements, “customer satisfaction” etc.

The idea that people depend on others to do their job is fine, but treating "process management" as exactly the same as an organisation producing goods and services for a customer is confusing when the standard uses the same terms for both situations (same comment applies to “product”).

The phrase “from the organization” creates a relationship which can be limiting with goods and services. Goods are different from services in this respect as the party that receives a service is usually the one that pays for it and uses it. In understanding customer needs organizations need to look beyond the person or organization that receives the goods and to the one that pays for it and more importantly the one that uses it as all three have different needs.

If the definition is changed as suggested we can dispense with the examples.

4.4 Definition of system

4.4.1 Proposition

The definition of system should be changed to:

“combination of interacting parts organized to achieve one or more stated purposes”.

Note 1: There are four basic types of systems;

deterministic: systems in which neither the parts nor the whole are purposeful (i.e. can determine their own purpose);

animated systems in which the whole is purposeful but the parts are not;

social: systems in which both the parts and the whole are purposeful;

ecological systems in which some of the parts have purposes but not the whole.

Note 2: An organization can be perceived to be a deterministic system, an animate system or a social system depending on the degree of choice given to the parts by the owners/managers.

4.4.2 Justification

The proposed definition is taken from ISO TR 15026:2010 except the term elements is replaced by parts as this is in line with generally accepted definitions in scientific and management literature although the precise wording varies. The key characteristics of a system are that it has a purpose which is fulfilled by the interaction of the parts, none of which have the same characteristics as the system.

4.5 Definition of management system

4.5.1 Proposition

The definition of management system should be changed to:

“combination of interacting parts organized to achieve one or more organizational objectives

Note 1. An organisation has only one primary management system of which other management systems form a part or sub-systems. These sub systems model certain parts of the way the organization functions.

Note 2. The primary management system comprises the network of processes and resources that define, generate and deliver the organization’s results.

4.5.2 Justification

The new definition builds on the definition of a system in 4.4..

The N123 definition implies that processes are not used to establish policies and objectives – only that they are used to achieve objectives.

N123 Note 2 is flawed because if the structure, roles and responsibilities, planning, operation are the interacting elements what possible role can processes have?

N123 Note 3 If by scope they mean system boundary and this can be less than the scope of the organization, this encourages reductionist thinking – devising “management systems” for .parts of the organization that operate separately from the whole.

4.6 Definition of quality management

4.6.1 Proposition

The definition of quality management should be changed to:

“a function of management that develops and manages the organization’s capability to deliver outputs that produce satisfied interested parties.

4.6.2 Justification

The act of directing and controlling an organization with regard to quality is in essence a function of management. As quality is the degree to which a set of inherent characteristics fulfils requirements, the gap between requirements and achievement needs to be managed and that is about managing capability, for when the organization is truly capable it will be delivering outputs that produce satisfied interested parties.

4.7 Definition of quality management system

4.7.1 Proposition

The definition of quality management system should be changed to:

“a system for developing and managing an organization’s capability to deliver outputs that produce satisfied interested parties. ”

4.7.2 Justification

The definition of quality management system needs to take as its source the definition of quality management in **Error! Reference source not found.**4.6.

4.8 Definition of stakeholder

4.8.1 Proposition

The terms interested party and stakeholder should be defined differently as follows:

“Stakeholder: person or organization that contributes to an organization’s capacity and capability and are its beneficiaries and/or risk takers.”

“interested party: person or group of people that holds a view that can affect the organization”.

Note: Elsewhere in this paper, only the term Interested party has been used.

4.8.2 Justification

A group having an interest in the performance or success of an organization might not be benevolent. This would include terrorists, competitors and others whose interest in the organisation may be malevolent and whose threats the organization needs to counteract. It would be absurd for organizations to set out to satisfy the needs and expectations of these stakeholders. However, they are interested parties that may threaten the success of the organization and therefore those threats need to be managed. This is part of risk management not stakeholder management.

4.9 Definition of outcome

4.9.1 Proposition

The following definition of the term outcome should be included in ISO 9000 section 3:

“indirect effects of an action, output, product, process or system”

Note: these effects might be the benefits derived from use of a product or the unintended consequences resulting from the product or the processes through which it was produced.”

4.9.2 Justification

There is no current definition in ISO 9000 but the term is used in the definitions of the process approach.

The concept of outcomes, and the need to manage them, is intrinsic to the management of risk and to process design and performance.

The process approach is defined in ISO 9001 as “The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”. This implies it is the interaction of processes that produces an outcome but of course it could be a single action that triggers a series of events that lead to a catastrophic outcome

4.10 Definition of product

4.10.1 Proposition

The definition of product should be changed as follows:

“goods or services produced or provided by an Organisation for the benefit of another organisation or person, often for payment”.

4.10.2 Justification

The extensive explanation in ISO 9000:2005 implies that a product is no different to an output. "Product realisation" must mean "realising the output from (any and every) process" using the current definitions, and so must include every process. If every output is a product it implies everywhere the word product occurs in ISO 9001 the corresponding requirements apply. This would be absurd, because it would apply the design, production, and corrective action, nonconforming material control requirement to management and supporting processes when this was not the intention.

"processed materials" suggests "materials which have gone through a process", ie a "product" or perhaps even an "Input". Or is it a different type of "process" in this case?

The examples and explanations are so random that they hinder rather than help. Software is instructions that cause a computer to function. It is not a dictionary, a driver's manual and in fact any document. This is not software but information. It would make nonsense of requirements containing the word software if it is intended that it refers to documents. It implies that where ISO 9001 refers to documents all of which are a product of a process, they are somehow software – quite absurd.

If the term output is used to refer to the result of a process, the term product can then be used to refer to the output of an organization thus removing the confusion. It would also avoid confusion when we refer to product specifications etc.

4.11 Definition of process

4.11.1 Proposition

The definition of process should be changed to the following:

"a set of related tasks triggered by an event and intended to achieve an objective.

4.11.2 Justification

Not all processes transform inputs into outputs and not all inputs are transformed. e.g., Resources are a process input but some are used, some are consumed and a few might be transformed. People are not transformed in a process unless they are being processed. Many processes simply take information and use it. The information remains the same afterwards – it is not transformed.

Processes are activated by some kind of trigger; a date, an event or an instruction, following which work is undertaken to produce a result which achieves an objective. Work is not done in an organization without any purpose.

4.12 Definition of policy

4.12.1 Proposition

The definition of policy should be changed to the following:

“intentions and principles which provide a framework and guidance for what the Organisation wants to achieve and how it will operate”.

4.12.2 Justification

Not all processes transform inputs into outputs and not all inputs are transformed. e.g., Resources are a process input but some are used, some are consumed and a few might be transformed. People are not transformed in a process unless they are being processed. Many processes simply take information and use it. The information remains the same afterwards – it is not transformed.

Processes are activated by some kind of trigger; a date, an event or an instruction, following which work is undertaken to produce a result which achieves an objective. Work is not done in an organization without any purpose.

4.13 Definition of preventive action

4.13.1 Proposition

The term “preventive action” should be removed from the ISO 9000 family and replaced with a section on risk management.”

4.13.2 Justification

This is intrinsic to risk management and planning. The concept should apply to many aspects of good management and should not be seen as an activity in its own right. In the High Level Structure N119 section 6.1.1 addresses “*Actions to address risks and opportunities*” and thus this would replace the section on preventive action in ISO 9001.

Many people including auditors confuse preventive action with that part of corrective action which addresses the prevention of recurrence and as a result, do not recognize its association with risk assessment and removal.

5 Structure

5.1 Harmonising revision cycles

5.1.1 Proposition

The revision cycles of ISO 9000, ISO 9001 and ISO 9004 should be harmonised so that terminology and concepts are brought into alignment.”

5.1.2 Justification

The revision cycles of the standards in the ISO 9000 series have got out of sync since the last major revision in 2000 and hence terminology and concepts in ISO 9000 are out of step with those in ISO 9001 and ISO 9004. E.g. the explanations of process approach and systems approach in ISO 9000 differ from those in ISO 9001 and new terms such as mission, vision, values and strategy introduced in ISO 9004 are not in ISO 9000 vocabulary nor used in ISO 9001. Ideally the concepts, principles and terms should precede their application so that ISO 9001 and ISO 9004 are based on these concepts and principles and use common terms. In addition there should be a stronger and more

coherent interrelationship between the concepts, principles, requirements, guides and vocabulary so that requirements are based on principles and concepts with principles derived from concepts and vocabulary maintained concurrently.

5.2 Title and scope of ISO 9000

5.2.1 Proposition

The term systems should be removed from the title and scope of ISO 9000 and that ISO 9000 be re-titled as Quality management – Fundamental concepts, principles and vocabulary.

5.2.2 Justification

The current title of ISO 9000 is Quality management systems – Fundamentals and vocabulary. The purpose of ISO 9000 is stated as to assist organizations, of all types and sizes, to implement and operate effective quality management systems. Its scope is stated as describing fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms.

The ISO 9000 family of standards are the only ISO standards dedicated to quality management and therefore provide a vehicle for the codification of principles and practice in quality management. Limiting the purpose and scope of the ISO 9000 to quality management systems narrows the boundaries such that ISO 9000 role as the foundation standard is undermined.

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