THE VANGUARD STANDARDS

A systems thinkers guide to interpretation and use of ISO 9000:2000*

******** WARNING ********

This document contains language and concepts that may be unfamiliar to the user. It is recommended that the user should read "The Case Against ISO 9000", second edition - in particular chapters 5 to 9 - to gain familiarity with the principles and practices of systems thinking as it applies to the design and management of work.

Recommended educational resources to support the use of The Vanguard Standards:

- ♦ The fundamentals of systems thinking (essential)

- ♦ Transition planning – how to move from ISO 9000 to ISO 9000: 2000, using the Vanguard Standards

- ♦ Auditor training – how to audit from a systems perspective

For further information about these and other educational resources, please go to **www.systemsthinking.co.uk**

THE VANGUARD STANDARDS

Introduction

With the advent of ISO 9000: 2000, our advice regarding ISO 9000 remains unchanged: registration to ISO 9000 should be avoided. However, many people feel they cannot avoid registration because they are coerced by customers into registration ('you comply or we won't buy).

If market-place coercion means that you cannot avoid registration to ISO 9000, we strongly recommend that you take a systems approach. That is the purpose of the Vanguard Standards, to help managers, consultants and assessors take a systems approach to ISO 9000 registration.

Some people will be surprised to learn that the Vanguard team has written these standards, after all, we have been the most vociferous critics of ISO 9000. It does not change our advice; ISO 9000 should be avoided. Standards and inspection are not the best route to take if you want to learn and improve.

We have used the principles and methods contained in the Vanguard Standards with clients who have wanted to take a systems approach and achieve registration to ISO 9000. They work very well. These methods also meet ISO 9000's requirements and are robust and generalisable - they work with all organisations regardless of size and sector.

Should you use the Vanguard Standards, it will require work with your assessor, for their use appears novel to assessors the first time they meet it. In one of our clients the assessor took his colleagues to the first inspection, having been surprised by the novelty of the approach during the pre-assessment visit. Bear in mind that a bad reaction from your assessor should not put you off. As we saw in the case studies reported in "The Case Against ISO 9000", assessors need to be and can be stood up to. In any event, ISO 9000 is difficult to "lose" – the assessors want your business. If you write this (systems) thinking in to your quality manual – **what you say you do** – and then ensure you put in place the measures and methods – **ensure you do it** – you will be able to withstand any inspection – **prove it**. The fundamental principles of ISO 9000: 2000 will be satisfied. En route you will make choices to exclude or reinterpret the requirements and guidance of ISO 9000; and you will be informed about how and why you have chosen to do so.

The Vanguard Standards should be read in conjunction with the ISO 9000 Standards. Because we have followed ISO 9000's paragraph structure, there is some duplication. This is left in as it may help clarify interpretation and use. Managers will find a more

user-friendly structure for the Vanguard model for "check" – understanding the what and why of performance as a system in "The Vanguard Guide to Business Excellence" and "The Vanguard Guide to Understanding your Organisation as a System" (see **www.systemsthinking.co.uk**).

John Seddon
October 2000

The Vanguard Standards

Vanguard 9001 is a systems thinker's interpretation of requirements for ISO 9001. Vanguard 9004 is a guide to interpretation and use of quality management (systems) thinking for performance improvement.

For ease of use, the requirements (Vanguard 9001) and guidance (Vanguard 9004) are written as one document. To distinguish **requirements** and advice, Vanguard 9001 is written in **bold**. To help the reader make comparisons with ISO 9000, the same paragraph structure and numbers[*] are used. Notes in italics comment on distinctions between the Vanguard and ISO Standards.

0 Introduction

0.1 General

Vanguard 9001: This presents requirements for a quality management system, based on a systems view of an organisation.

Vanguard 9004: This provides guidance on the application of Vanguard 9001 for performance improvement.

Vanguard 9004 (general guidance):

The existing framework of responsibility, authority, measures, reporting lines and relationships related to receiving and fulfilling customer demand is the operational management system in place. The operational management system in place is an organisation's quality management system.

The phrase 'quality management system' should not be interpreted as referring to anything other than the perspective, principles and practice of organisational/work design and management that currently constitute the operational management system.

The principles of design and management advocated by this Standard for the achievement of performance improvement derive from the adoption of: a system (systemic) perspective, the theory of variation, the discipline of (organisational) learning and the nature of motivation. Together, these four elements provide a theoretical and operational position radically different from traditional management thinking and practice.

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[*] ISO 9004 has more sub-clauses than ISO 9001. As we follow the ISO clause structure, some clauses only have guidance and no requirements.

This Standard advocates that the purpose of any organisation is the continuous improvement of its capability to <u>create customer satisfaction,</u> <u>improve efficiency</u> and <u>increase revenue</u>.

The perspective, principles and practice advocated by this Standard are applicable to all organisations, irrespective of size and/or markets.

0.2 System model

Vanguard 9001: All organisations are systems, whether they are managed as such or not. For an organisation to be managed for improvement, a systems perspective is the most effective means.

Figure 1 gives a conceptual presentation of the Vanguard model for understanding the organisation as a system:
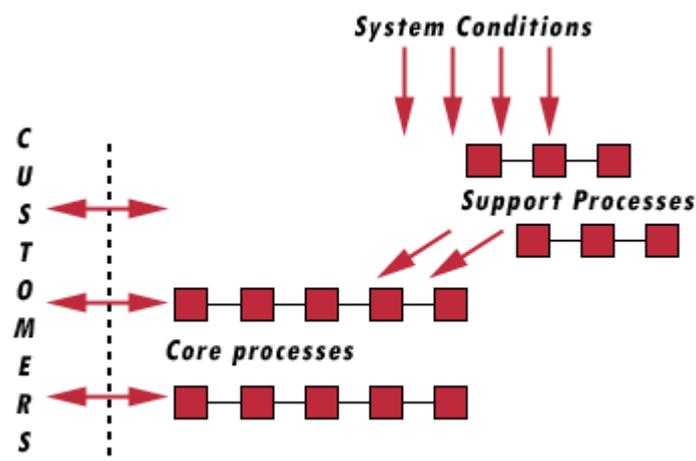

Figure 1: The Vanguard Model for understanding the organisation as a system

> Note: *This model is fundamentally different from the process model shown in ISO 9000. The Vanguard model ensures that all management activity is understood from the point of view of its impact on the work, as seen from the customers' point of view. This is to start change at 'check' in a cycle of 'check-plan-do' rather than 'plan' in the 'plan-do-check-act' cycle.*

Vanguard 9004 (guidance): We have found the Vanguard model for understanding the organisation as a system to be robust across all organisations regardless of size or sector. The value of the model is that it subordinates all management activity to the organisation's core work. This is a significant advantage in as much as other models – the ISO 9000 process model being one example – encourage managers to engage in activities without first gaining a concrete understanding of the relationship between the activity and the organisation's purpose. The consequence is wasteful and counterproductive activity.

At the macro level, the organisation's core and support processes are defined by looking outside-in. At the micro level the work within any process should be viewed from the process' end-to-end perspective.

The performance of a process, whether macro or micro, is subject to the influence of many factors – system conditions – in its organisational and business environment. These affect capability or achievement of purpose and cause <u>variation</u> in performance.

The factors in the organisational environment that can influence the operational performance of a process are many:

- how well what matters to customers is understood

- how well the nature of customer demands on the system are understood

- product, service, process and organisation design

- information, nature and availability

- what is measured and how measures are used

- the effectiveness of training

- what is rewarded

and so on.

The point of integration of many of these possible factors lies in the way managers think about the design and management of work. <u>Understanding the "what and why" of current performance as a system is the essential prerequisite to improving performance.</u>

To improve process performance the system factors that govern current performance must be first understood and action continually taken to reduce the variation in performance they cause. Management's job is best defined as <u>action on the system to achieve improved system and process performance.</u>

An organisation's quality management system is not about compliance but about competence: the competence it demonstrates in achieving improved performance for customers, the organisation and associated stakeholders, through management of the system.

1 Scope – requirements

1.1 General

Vanguard 9001: This Standard specifies requirements for a quality management system where an organisation needs to demonstrate its capability to understand and improve the provision of services and/or products to customers.

> *Note: The difference between this and ISO 9001 is the emphasis on understanding and improvement over 'consistency' and 'conformity'.*

Vanguard 9004: This Standard provides guidance on how to how to manage an organisation to achieve continual improvement in <u>satisfaction</u>, <u>efficiency</u> and <u>revenue</u>.

1.2 Application

Vanguard 9001: The Vanguard model is generic and applicable to all organisations.

In its application of ISO 9000, management may choose to exclude some of ISO 9001's clause 7 requirements.

Vanguard 9004 (guidance): We have yet to find the boundaries for the use of the Vanguard model (figure 1). While in some applications the labels have been changed, the principles have been shown to be robust and generalisable.

The user of the Vanguard Standard may seek to reduce the scope of ISO 9001(clause 7), in terms of how it should apply to their business and thus how the business should be assessed. It is also likely that the user of the Vanguard Standard will choose to interpret ISO 9001 in particular ways, given that the Vanguard Standard takes a systems perspective of all ISO 9000 clauses.

Both reduction in scope and interpretation of ISO 9001 should be considered after application of the Vanguard Standard to the business as this will lead to informed discussion and decisions. The user will also be in a position to discuss these issues with the chosen assessor.

2 Normative reference

and

3 Terms and definitions
The language of systems thinking has been used consistently throughout these Standards, in "The Case Against ISO 9000" and in all Vanguard guides, manuals, books, tactics and articles.

4 Quality management system

4.1 General requirements

Vanguard 9001: The organisation shall be defined as a system, showing:
- **Overall purpose, in customer terms**
- **Core processes**
- **Major support processes**
- **Measures of all core and major support processes; showing current capability**

> *Note:* *This is consistent with ISO 9001, except to note that ISO 9004 (guidance) presents quality management as one of a number of management disciplines. The Vanguard Standard does not make this distinction – quality management, if based on a systems perspective, represents the whole of management's work in managing and improving performance.*

Vanguard 9004 (guidance): The above model is consistent with a systems thinking interpretation of the eight quality management principles identified by ISO 9004: customer focused organisation; leadership; involvement of people; process approach; system approach to management; continual improvement; factual approach to decision-making; mutually beneficial supplier relationships. The Vanguard model ensures that the organisation's core processes are defined 'outside-in' – from the customers' point of view. Similarly, the organisation's support processes must be understood and managed from the point of view of how they impact core processes. It is of vital importance that the core and major support processes are measured and measures must show capability versus purpose.

In the above ways, the organisation's management will be focused clearly on the organisation's capability and thus the factors affecting capability. In following all of ISO 9000's subsequent requirements, the managers of an organisation should relate them to this model.

> Note: ISO 9001 *includes* a note (guidance for clarification) indicating that processes should include processes for management activities, provision of resources and measurement. All of these should not be considered without reference to their influence on the core and support processes of the organisation. To treat such activities as processes in their own right can easily lead to unnecessary and wasteful work.

Focus on purpose, measures, methods:

Quality is (simply) a measure of achievement of purpose.

To know what your current quality is and, more importantly to improve it, requires an operational understanding of <u>purpose</u> and an operational <u>measure</u> of achievement of purpose. Improvement then requires action on the <u>methods</u> currently in use.

These are the three essential elements of effective management and leadership. If the requirements of the Standard are understood or applied in any manner that obscures the clarity of these three elements the Standard itself will fail to achieve its purpose. This can happen if the term "quality management system" is perceived as something in addition to, in parallel with, as distinct from the day to day line management of the organisation. This can also happen if methods are treated as more important than measures and purpose, as has been the case in so many applications of ISO 9000.

<u>Clarity of purpose</u> refers to the publicised product and/or service the organisation offers. The refinement of an organisation's understanding and expression of purpose is dependent upon the refinement of their customer relationship – excellent organisations are designed and managed according to what matters to their customers.

Organisations are sometimes unconscious of a dichotomy within their operation between a public (espoused) statement of purpose and a 'de facto' purpose created by a failure to relate measurement and methods to the espoused purpose. Such a dichotomy often becomes clear when managers study their organisation as a system.

<u>Measurement</u> refers to the operational data, which tells the organisation how good it currently is in achieving its purpose. Capability measures show the predictability of performance and, thus, can be used to track improvement.

<u>Method</u> refers to the (end-to-end) chain of activities that link the identification of customer requirements through to delivery to the customer's complete satisfaction. Such end-to-end chains are referred to as core processes and may cross several functional interfaces, including supplier interfaces. Other chains of activities may constitute support processes to the core processes e.g. finance, IT, HR, procurement, facilities management etc.

These three key elements of management/leadership are universal, applying to organisations of all sizes, complexity or type. They equally apply at the macro and micro level of operation.

The first and overriding requirement of a management system related to quality is that it actually helps the organisation improve the effectiveness and efficiency of its product and service delivery to its customers. The documentation of such a system is the <u>minimal</u> required to help understanding and demonstrate improvement.

The second requirement is that it reflects an outside-in perspective of the organisation's operations. This means that all functional activities are understood, measured, managed and represented as part of an end-to-end work flow that conditions the organisation's current capability to service its points of transaction with its customers.

In effect, the organisation should be understood, managed and led from a systems perspective.

The third requirement is that it maintains a clear distinction between process (flow) and procedure. Understanding, measuring and managing activities as part of end-to-end flows and using knowledge of such flows to aid improvement activities is fundamental. Knowledge is derived from the use of measures and sufficient understanding of the flow and system from which to be able to theorise about the scope and means of improvement.

Documenting a procedure or instruction is helpful only when it is judged that without a written procedure or instruction performance is at risk; or health and safety require it.

4.2 Documentation requirements

4.2.1 General

Vanguard 9001: The quality management system documentation shall include:

a) A system picture describing the organisation's purpose, core and support processes
b) Policy statements regarding documentation, roles, measures, records and training

Vanguard 9004 (guidance): There should be only one quality manual, including all of the above. The following are recommended policy statements:

Documentation: The quality manual indicates where documents will be found. Up-to-date documents are held where the work is done.

> *Note: This will eliminate the bureaucracy of document control.*

Roles: Roles are designed to ensure that people who do the work are in control of and responsible for improving their work; management roles are designed to add value to the work.

Measures: Measures relating to purpose are held by those who do the work and used for understanding and improving the work. The same measures are used by managers to understand and improve the work from their different and complementary perspective.

Records: Only those records that are critical to the performance of the work will be kept.

Training: Training is treated as a preventative measure, people being trained and assessed as competent prior to being placed in positions of responsibility.

4.2.2 Quality manual

Vanguard 9001: The organisation shall prepare a quality manual.

The quality manual shall include:

A statement of the organisation's philosophy of quality with respect to the requirements of product and service delivery

A system picture that should include:
♦ **A flow presentation of its core, end-to-end, processes together with an operational statement of purpose and operational measures of achievement for each**
♦ **A flow presentation of each support process together with an operational statement of purpose and operational measures of contribution for each**
♦ **Related statements of policy with regard to engagement of all employees, training and development, internal audit and accountability**

If judged possible, there should be only one quality manual.

> *Note: The requirement to have only one quality manual is a major difference with ISO 9001. This will obviate the excessive bureaucracy associated with document control.*

Vanguard 9004 (guidance): The system picture referred to in "Quality management system requirements" (4) should constitute the major part of any quality manual. Particular information regarding core flows, key measures and commonly used information regarding method(s) should be <u>held in the</u> <u>core and support processes</u> - the quality manual should indicate that the version-in-use will be found there. Thus the quality manual only needs to indicate the core and support processes, stating their purposes, measures and high-level-flows.

4.2.3 Control of documents

Vanguard 9001:   Documents shall be controlled where they are used (see above)

4.2.4 Control of quality records

Vanguard 9001: The organisation shall maintain only such records as are necessary for managing the core and support processes. Records shall be maintained where they are used.

4.3 Quality management principles

Vanguard 9004 (guidance): The following principles of design and management describe the means by which ISO 9000's quality management principles are best operationalised:

♦ The customer sets the <u>nominal value</u> to be fulfilled

♦ Design versus demand: The organisation is designed and managed from the <u>'outside in'</u> in that the customer's nominal value is the organisation's operational goal

♦ <u>Expertise – determined against demand – at the point of transaction</u> establishes optimum flow for demand

♦ The activities or steps within each flow are <u>only those which add value</u> for the customer

♦ The role of management/leadership is to <u>understand and act on the organisation as a system</u> in order to continually improve the design and flow of its processes and their capability to deliver the customer's nominal value

♦ <u>Measures of capability</u> (to deliver nominal value) are used as the key and permanent measures of performance and improvement

♦ Measures of capability are <u>in the hands of those who 'do the work'</u>

♦ Work and recognition is designed in accordance with the requirements of <u>intrinsic motivation</u>

♦ All decision making is <u>data based</u>

> *Note:*   *These principles differ from but are consistent with ISO 9000's quality management principles. The Vanguard Principles provide a stronger operational focus for the quality management system*

Managing the system and its processes

Vanguard 9004 (guidance): The term 'process' may be applied at the macro and/or the micro level of organisational activities. But it does not help understanding and practice to employ the term 'system' at the macro and micro level in the same way. To speak of many systems within an organisation is to risk perpetuating the traditional 'functional' mentality under a different name. The organisation and its external environment is the system in which all its processes, macro or micro, operate, subject to the multiple influences of the system. There being one system establishes the requirement to view the macro processes as end-to-end flows focused on fulfilment of the customer's nominal value. Such end-to-end flows should include, where appropriate, supplier processes.

It may be that with respect to an individual process, it is not easy, or even useful, to explore the real time influence of elements in the macro definition of its system. For

example, the influence of investors on the performance of an assembly process, or that of competitors on a change of address process. (The influence of elements in the macro definition of the system may be more strategic in nature). Nonetheless, every process is potentially subject to influence from any or all factors within the organisation's macro system. It is the role of management to identify real time influences from whatever source (more 'immediate' factors such as process and work design, measures in use, issues of flow etc. will be more commonly addressed by the majority of managers) and take appropriate action to safeguard and improve the process' performance.

Evaluation of the organisation's progression in performance improvement

Vanguard 9004 (guidance): The principles on which this Standard is constructed will guide an organisation towards continuous improvement of performance.

These principles apply to all types and sizes of organisations, whether in the manufacturing or service industries.

Continuous investigation of the "what and why" of current performance, together with measures of capability provide the only valid evidence of performance improvement and are the continuous markers of self assessment.

In essence, a management system related to quality should give evidence that the organisation measures its current capability to completely satisfy its customers and is continually refining its methods in order to improve performance.

5 Management responsibility

5.1 Management commitment

Vanguard 9001: Top management should lead the organisation in the pursuit of its purpose. The system picture created should be used to provide clarity to all in terms of purpose and measures (achievement of purpose). The quality management system should be the only management system, there being no distinction between "quality" and "business management".

> *Note:*   *ISO 9001 tells managers they should "provide evidence of … commitment to the development and implementation of the quality management system" by establishing policy, communication, review and provision of resources. In our view, the wording of ISO 9001 reflects traditional hierarchical assumptions. However, the requirements of ISO 9001 can be met as written by using the Vanguard Standard. There is no substantial conflict.*

ISO 9001's requirements for communication and policy can be met with the development and communication of the system picture. The over-riding objective is to improve capability – arbitrary targets should be avoided. Management review should be achieved through hands-on-leadership, not bureaucratic meetings. The availability of resources should likewise be managed from the point of view of their impact on process performance - a bureaucracy for resource management should be avoided.

5.1.1 Introduction

Vanguard 9004 (guidance): Top management shall demonstrate its commitment by ensuring that:

The organisation's philosophy of quality is clearly formulated on the acceptance that its quality management system is (simply) the way the organisation does business. The organisation should be:

♦ Customer focused and improvement driven: giving the customer what they want in the most efficient way
♦ Designed and managed as end-to-end flows servicing the points of transaction with the customer
♦ Measured through achievement against purpose, using these measures to understand and improve method(s)

The responsibility of management/leadership can be summarised as:

♦ Ensuring clarity of operational <u>purpose</u>
♦ Seeking operational learning from <u>measures</u> related to purpose and studying, therefore, the "what and why" of performance
♦ Experimenting with <u>method</u> to improve performance

<u>The purpose of management is to lead.</u> This can only mean leading towards achievement of purpose, measuring to understand the predictability of the operation to achieve purpose and experimenting with method to improve its capability to achieve purpose. Leadership is potentially the responsibility of everyone in an organisation, according to operational need.

Senior management have the added responsibility to ensure that operational accountability in all roles is exercised and appraised against the threefold focii of <u>purpose, measures, method.</u> The <u>competence</u> of the organisation's management is reflected in measures of <u>satisfaction, efficiency and revenue.</u>

> Note: This guidance differs from ISO 9004 in that our emphasis is on "leadership through learning" rather than "management by plan,

deploy, inspect and improve". Our emphasis is on 'check-plan-do' rather than 'plan-do-check-act'.

Furthermore, ISO 9004 advises a number of leadership activities (e.g. vision, values, benchmarking) which can often lead to counter-productive activities.

5.1.2 Issues to be considered

Vanguard 9004 (guidance): The senior leadership of the organisation must provide a clear operational description of "quality" for the organisation, making it the foundation of all organisational norms related to managing and improving business performance.

The top leadership should require that:

The end-to-end (macro) processes that constitute the organisation's cross functional (including suppliers) activities related to fulfilling the customer's nominal value are understood and managed from the same, end-to-end, point of view.

Planning, decision-making, change and appraisal should be data based.

Measures related to achievement of purpose are valued, owned and acted upon by those who do the work and managers together.

> *Note:* *Again this is a difference in emphasis. ISO 9004 encourages a 'top-down' emphasis, advising promotion of policy, planning, objectives and communication. Two examples:*
>
> *ISO 9004 advises that "process inputs, activities and outputs are clearly defined and controlled". This is to focus on specification and control. The better starting place is to measure the capability of a process, end-to-end and from the customers' point of view. Such a measure would lead managers and staff to question what affects capability and, thus, what inputs, activities and outputs might require attention. The result is understanding and, hence, better control.*
>
> *ISO 9004 advises that process owners should be identified and given full responsibility and authority. It is not unusual to find such roles competing unsuccessfully with traditional functional roles that focus on functional measures. Roles and measures should ensure the organisation is managed as a system, with management roles attending to the management of core and support processes using measures related to purpose.*
>
> *There is no substitute for leadership.*

5.2 Customer focus

Vanguard 9001: Top management should ensure that the organisation employs reliable methods to ensure it understands what matters to its customers and translates the same into actions and operational measures.

> *Note:* *This is consistent with ISO 9001. Documentation of method(s), data and used data should be maintained only at the point of use.*

5.2 Needs and expectations of interested parties

5.2.1 General

Vanguard 9004 (guidance): While it is true that every organisation has several categories of interested parties, for example, customers, people in the organisation, owners, investors, suppliers, partners, society; a firm focus on the customer serves all parties.

> *Note:* *ISO 9004 conceptualises such needs as requiring a "balanced response" to the parties' needs. This is indicative of compartmentalisation, a feature of "command and control" thinking. Systems thinking shows that as quality improves, costs fall. The means for improvement should be with the people who do the work - people are always motivated to improve what they do. The same attitude should be conveyed to suppliers. Systems thinking provides the means to manage in a way that meets the needs of interested parties.*

5.2.2 Needs and expectations

Vanguard 9004 (guidance): The needs and expectations of all parties - the organisation, its people, owners, shareholders, suppliers and partners - are best served through focussing on customers.

The success and indeed the long-term growth and/or survival of an organisation is critically dependent upon how well it understands its customers. In particular:

♦ How well it understands the processes by which it aquires customers
♦ How well it understands the contribution its products and/or services currently provide to their customer's achievement of purpose
♦ How its products or services might be developed to offer increased contribution/value to customers
♦ How well it understands the criteria customers use to judge the organisation's performance as a product/service provider

In response to these considerations, an organisation should:

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- Clarify and confirm the main customer acquisition and customer service processes
- Establish appropriate categories of its customers
- Engage customers in each category in exploration of what matters to them - to determine the nominal value
- Install the customer's criteria of (quality) performance as its own operational goals

People's motivation and commitment are essential to operational success, learning and improvement. People's needs are best served by creating value in their work through clarity of purpose and measures relating to purpose in their hands. Pride (intrinsic motivation) is the consequence.

> *Note:* *ISO 9004's guidance may lead managers to make ineffective and wasteful interventions in terms of 'recognition, work satisfaction, competencies, knowledge management, involvement and motivation'. Care in interpretation is advised.*

Owners and investors: It is in the investors' or owners' interests that the organisation learns how to get and keep customers.

Suppliers: In so far as suppliers share or can be encouraged to share an attitude of co-operation, they should be treated as working jointly on end-to-end process performance.

Health, safety and the environment: In ways that are deemed appropriate to the particular organisation, management should ensure responsibility is taken to act in ways that are responsible with regard to health and safety and the environment.

5.3 Quality policy

Vanguard 9001: Top management shall establish its quality policy.

Vanguard 9004 (guidance): To declare that the organisation will be understood and managed as a system with the following features:

- Customer-driven
- Improvement-driven
- System picture
- Understood by all
- Underpinning all activity

..is a sufficient quality policy. To employ these features would be to work outside-in, developing key measures and methods from the customers' point of view.

> *Note:* *This would meet all of ISO 9001's requirements.*

Top management shall establish the quality policy and ensure that it:

♦ Specifies the organisation's core processes from the points of transaction with the customer
♦ Defines achievement of purpose as the cornerstone of its measurement system
♦ Requires operational measures to be used as the foundation for improving performance
♦ Treats effectiveness and efficiency as the co-principles of quality
♦ Sets contribution to the improvement of the workflow as a norm for those who do the work and managers alike
♦ Requires documentation of method only where effectiveness or efficiency are demonstrably at risk without it
♦ Is understood and respected by all employees

An organisation's quality policy is the cornerstone of all other policies in that it gives expression to the organisation's central philosophy of how to design and manage a business in the mutual interests of customers, investors, suppliers, partners, people in the organisation and society.

This statement of policy has a logical priority over every other quality requirement or activity. It presents the principles of design and operation which are to determine the norms of how the business is to be managed and improved. It is not a policy in parallel to, or as distinct from how the business is to be or, de facto, is being run: it is a statement of conviction about the best way to grow and prosper the organisation for the benefit of all interested parties.

5.4 Planning

Vanguard 9001: Organisational planning should be based firmly in an understanding of the "what and why" of current performance as a system. This is to start all management work at "check" rather than "plan". It follows that any plans should include predictions of outcomes.

> *Note:* *Although ISO 9001 is likely to encourage managers to start at "plan" rather than "check", this interpretation should result in no difficulties with an assessor.*

5.4.1 Quality objectives

Vanguard 9001: Objectives shall be set in general terms of improved achievement of purpose.

Vanguard 9004 (guidance): The objective of each contributing function or activity in the end-to-end core process shall be set in terms of the continuous improvement of its product/service delivery, i.e. it should relate directly to end-to-end capability of the core process(es).

The objective for each support process shall be set in terms of the continuous improvement of the support it provides to the operational performance of the core processes.

The organisation shall have only one, unchanging quality objective, common to every process within and across functions - improved capability.

> *Note:* ISO 9001 states that quality objectives should be established at each **relevant** function and level. The systems view should be argued to be the means for determining **relevant**. "Function" and "level" are command and control concepts. To establish goals that are, in any sense, at odds with managing end-to-end flow will risk causing sub-optimisation.

Vanguard 9004 (guidance): There is no value in using targets. A target is an arbitrary goal. By working on the "what and why" of performance, managers should be able to predict the consequence of change(s). Prediction is the hallmark of systems thinking. By contrast, the use of targets in a hierarchical organisation often causes people's ingenuity to be employed in surviving in or fighting the system. In short, targets cause waste and obviate learning and improvement. Avoid them.

5.4.2 Quality management system planning

Vanguard 9001: Quality management system planning shall be undertaken as part of a continuous check-plan-do cycle.

Vanguard 9004 (guidance): <u>Check</u> refers to the initial step of establishing an informed understanding of the "what and why" of current performance as a system; <u>plan</u> refers to the decision on where and how to change the current situation and involves a prediction of expected improvement with associated measurement. <u>Do</u> refers to the implementation with reference to the measure of <u>predicted</u> improvement and returns the planning process to <u>check</u>.

Quality planning conducted according to the check-plan-do cycle with associated measurement ensures that organisational change is conducted in a controlled manner. It is data based, improvement driven and guided by measures and is the heart of an organisation's determination to deliver to customer needs and wants more efficiently.

Quality planning is synonymous with the responsibilities and activities of line management. Reviewing quality plans is synonymous with the check-plan-do cycle of management activity, in that measures over time reveal the effectiveness of implemented change and prompt ongoing planning of change for (continuous) improvement. Reviewing performance should be thought of as a leadership activity, not "hierarchical, presentations and meetings" activities.

5.5 Responsibility, authority and communication

5.5.1 Responsibility & authority

Vanguard 9001: The organisation shall treat the management of its operations as its quality management system: focused on giving the customer what they want in the most efficient way. The primary purpose of a quality management system thus defined is improving product/service capability.

Note: *This interpretation can be argued to be consistent with ISO 9001. However, many will be influenced by ISO 9001 to establish a separate quality management system. This is wasteful.*

Vanguard 9001: All roles and measures should be defined by the requirement to understand and manage the organisation as a system, from an outside-in perspective, focused on the improving the performance capability of end-to-end fulfilment processes.

Vanguard 9004 (guidance): All roles, responsibilities and authorities must be designed from the basic system picture – ensuring all personnel have the scope to contribute to improvement of the organisation's achievement of purpose. All roles should have associated measures – relating to purpose – such that people have freedom to develop and improve method(s) of operation. Hence it is vital that measures should be integrated with work.

Responsibility to champion change for improvement rests with everybody in the organisation, without prejudice to any chosen arrangements for "authorisation". All responsibilities and authority must be related to improving achievement of purpose, which requires they be related to process rather than to function. The organisation should identify the nature, levels and (only) the number of responsibilities required to pursue continuous improvement of its core and support processes.

Those who do the work together with their managers shall identify and own the measures of improvement allowing a greater degree of freedom for internal entrepreneurial behaviour than in a command and control environment.

5.5.2 Management representative

Vanguard 9001: The management 'representative' is any and all managers 'in situ'; who are responsible for all activities required to understand and thus improve performance capability.

Vanguard 9004 (guidance): The line managers are the representatives of the organisation's quality system. Leading and engaging their staff, theirs is the responsibility to understand the level and causes of variation in current performance and to act on the system for improvement. The kernel of an effective quality system is an understanding of how the work currently works, leading to informed change to improve it. This is a leadership responsibility, not a representative activity.

5.5.3 Internal communication

Vanguard 9001: Timely communication related to the check-plan-do cycle of change and improved capability is the responsibility of the manager 'in situ' as part of an open culture of learning and co-operation among staff, between functions, with partners and suppliers, customers and investors, as appropriate.

Note: *ISO 9001 requires the establishment of processes for communication. Separate methods and procedures for communication should be avoided (as they are wasteful). The process, if it needs to be stated, is: 'leaders work with their people on purpose, measures and methods'.*

Vanguard 9004 (guidance): It is line management's task to ensure effective communication in support of improving operational performance. The existence of the system picture, roles and measures will be central to effective communications.

Effective lines of communication should be established in support of the improvement of operational performance. It is the responsibility of senior management to ensure that the data required to continuously improve performance are available to, owned and used by those who do the work and that, as needed, any other part of the organisation is collaborating in providing such data. Also, senior management is to ensure that data on the "what and why" of current performance are driving change.

5.6 Management review

5.6.1 General

Vanguard 9001: Management should review performance. By review is meant the day to day activities of management - clarifying purpose, measuring achievement of purpose and acting on the system to improve method. Management should not become detached from the work.

ISO 9001 requires that records be maintained for management reviews. You should avoid creating a review bureaucracy. Start instead with the assumption that the measures being attended to constitute the prime information for any records. Such records are as required by those who do the work.

Vanguard 9004 (guidance): Management review is a normal and constant activity and should centre around the system picture and measures thereon. Managers should ensure that decision-making remains integrated with work.

Management review is synonymous with the (continuous) operational review of current capability to achieve purpose and the "what and why" of planned change to improve achievement of purpose: check-plan-do.

Systems thinking dictates that management and decision-making is integrated with work. Hence managers should spend their time with the people who do the work, paying attention to: clarity of purpose, the operational implications of customer feedback, what the measures of current performance reveal, what is being learned from the activities of "check" and working to improve supplier capability. Any changes should be planned with predictions for improvement.

5.6.2 and 5.6.3 Review input and output

Vanguard 9001: Operationally focused, a management review will reference measures in use with respect to (as appropriate): customer satisfaction, capability data, waste in process flows (including supplier's), change requirements with respect to product or process design, resource and training requirements, predicting improvement to product or service delivery and changing system conditions that are demonstrably limiting achievement of purpose.

The operational review should lead to appropriate action (on the system) to improve achievement of purpose.

Note: *ISO 9001 lists a number of inputs that "shall be included". The system picture will help managers determine the vital few. Again, managers should avoid creating or reviewing bureaucracy. Hands-on leadership is the better alternative. ISO 9001 also requires output from a review - improvement decisions, actions, improvement achieved, resources required. Again, the primary focus for outputs*

should be the system's primary measures. Clauses 5.6.2 and 5.6.3 of ISO 9001 could easily lead to documents that serve the purpose of the assessor. Ensure that any documented reviews only serve the purpose of the system.

6 Resource management

6.1 Provision of resources

Vanguard 9001: The organisation shall determine and provide, as it judges appropriate, the resources needed to establish, maintain and improve product and service delivery to its customers. The requirements for resources shall be determined by reference to the system picture and, in particular, the organisation's core processes.

> *Note: This is to avoid resources becoming managed in their own right, and procedures and documentation being developed for the same, something ISO 9001 may encourage. If resources are managed without a clear understanding of the relationship with the organisation's core processes, waste and other forms of sub-optimisation could occur. This problem is often manifest in managing information technology when the technology is managed in its own right as opposed to its contribution to core process performance.*

6.1.1 Introduction

Vanguard 9004 (guidance): The management of all resources should be conducted from the point of view of how resources impact the performance of the system and hence the system picture developed by managers should be central to resource management discussions. Hence:

♦ Assignment and training of personnel
♦ Information
♦ Infrastructure
♦ Work environment

and any other resources should all be related to the basic system picture and it's elements.

The availability, development or acquisition of resources is an integral part of management's review of current performance and/or strategic planning, both of which are served by the cycle of check-plan-do.

6.1.2 Issues to be considered

Vanguard 9004 (guidance): Issues to be considered will be identified by the check-plan-do cycle of measurement, analysis and planning. The issues may relate to immediate requirements to safeguard or improve performance or be related to strategic requirements.

6.2 Human resources

6.2.1 General

Vanguard 9001: The organisation shall require line managers to ensure that the people they manage are competent on the basis of relevant education, training, skills and experience.

> *Note:* *This is consistent with ISO 9001 and emphasises competence of personnel to be a line management responsibility.*

Vanguard 9004 (guidance): Competence must be defined in operational terms. It should not be assumed that training and education are best achieved in the classroom. Often 'in-situ' training and education has advantages in terms of speed and relevance.

6.2.1 Involvement of people

Vanguard 9004 (guidance): The effective involvement of people in the achievement of purpose and the continuous improvement of the capability to achieve purpose is dependent upon the degree to which work and responsibilities are designed in accordance with the principles of intrinsic motivation.

This Standard recognises that motivation and involvement are directly dependent upon the value placed in work and that self sustaining and enduring motivation is generated by motivation intrinsic to the actual doing of the work.

This establishes a prior requirement that work is designed and managed as end-to-end flows and the associated measures are in the hands of the people doing the work.

> *Note:* *To follow ISO 9004's guidance re involvement of people could risk managing people issues independently of an understanding of the relationship between 'people issues' and the design and management of work. For example, measures of staff satisfaction are measures of symptoms and should not be acted on without an understanding of the causes. Care should be exercised if following ISO 9004's guidance.*

6.2.2 Competence, awareness and training competency

Vanguard 9001: The organisation shall require line managers to:

a) determine competency and training needs against an operational profile of exemplary performance

b) provide training and/or job aids according to the operational requirement

c) evaluate the effectiveness of any training provided with reference to operational performance

d) maintain only appropriate (as needed) records of education, training, skills and experience

> *Note:* *This differs in emphasis from ISO 9001 in that (a) above, we advise that managers determine operational criteria. In (c) we emphasise evaluation as requiring operational measures and in (d) we advise minimum records – only those that are useful to the organisation.*

Vanguard 9004 (guidance): Managers should be cautious not to assume that performance is governed by people – a notion that leads to wasted expenditure on training – it is governed by the system. Training should focus on 'how the work works'.

6.2.2.1 Competence

Vanguard 9004 (guidance): Competence should be defined in terms of exemplary performance.

Management should be responsible for ensuring that the work is designed in accordance with the principles of intrinsic motivation, that people have an unambiguous, operational understanding of what constitutes exemplary performance and are provided with the optimum tools to achieve exemplary performance.

The knowledge and skills required for exemplary performance serve as objectives for recruitment and training.

Managers should be responsible for updating the operational description of competence with related knowledge and skills as improvement to performance capability may dictate.

6.2.3.2 Awareness and Training

Vanguard 9004 (guidance): Exemplary performance for achievement of purpose is the quality objective of all training. Training should be provided only when prior investigation determines that unacceptable performance is not the consequence of:

- Contrary incentives
- Uncertainty about what competent performance looks like (in operational terms)
- Tools that are less than optimal
- Or that acceptable performance could be achieved with the support of some form of prophylactic support.

> *Note: This is to start at 'check'.   ISO 9004 advises consideration of a number of interventions that could be wasteful.*

6.3 Infrastructure

Vanguard 9001:   The organisation shall identify, provide and maintain the infrastructure it needs to manage and improve product/service quality.

> *Note: Our emphasis is manage and improve rather than "conform".*

Vanguard 9004 (guidance): The facilities required to achieve purpose may include items such as plant, workspace, hardware, software, tools, equipment, transport, etc.

The purpose of such items as are required is the effective fulfilment of customer demand. Their acquisition must be planned, their contribution measured and, where necessary, improved from that perspective.

Care should be taken to avoid excessive control and bureaucracy. An understanding of operations ('check') will point to the key facilities that need managing.

> *Note: Again, ISO 9004 suggests infrastructure includes a range of issues to be managed. Starting at check will determine the vital few that matter in your particular circumstances.*

6.4 Work environment

Vanguard 9001:   The organisation shall identify and manage the human and physical factors of the work environment only as deemed necessary – the primary concern of management being those factors that may have a detrimental impact on performance.

Vanguard 9004 (guidance): By work environment is meant the multiplicity of factors such as: noise, heat, light, hygiene, humidity, vibration, pollution, facilities, ergonomics, interpersonal relationships, organisation policies and administration.

Items such as these are all parts of the organisation as a system with the potential of conditioning motivation and contribution to achievement of purpose. They are all potential items for exploration and action as part of management's check-plan-do cycle for improved performance. However, care should be taken to avoid excessive control and bureaucracy. An understanding of operations ('check') will point to key factors in the work environment that need managing.

6.5 Information

Vanguard 9004 (guidance): The organisation shall determine the information necessary to demonstrate its performance over time in relation to achievement of purpose. To improve the performance of its core and support processes it shall require the documentation of operational statements of purpose, related measures of achievement and the workflow required to satisfy customer demands.

Such information typically includes:

♦ Outcomes of collaboration with customers on how well products/services fulfil what matters to customers
♦ Measures of customers' current satisfaction
♦ Measures of the organisation's current capability to create value for the customer
♦ Data related to the causes of inefficiency within the organisation's end-to-end processes and support processes
♦ Predictive data related to planned change

6.6 Suppliers and partnerships

Vanguard 9004 (guidance): Suppliers and partners are an integral part of the organisation's system. Everything that has been said about understanding, managing and improving the product or service capability applies equally to the integration of suppliers and partners in the achievement of purpose.

Organisations should seek to work with those suppliers and/or partners that have a co-operative attitude and share or wish to develop the same (system) thinking on the design, management and improvement of operations.

6.7 Natural resources

Vanguard 9004 (guidance): An organisation should have contingency plans against non availability with respect to natural resources only if this is deemed appropriate by management.

6.8 Financial resources

Vanguard 9004 (guidance): The purpose of Finance is to input sound financial and accounting information into the organisation's decisions about change and investment required to safeguard and/or improve product and service capability.

Financial results are a measure of current efficiency and capability to achieve purpose and are data relevant to the check-plan-do cycle of improvement.

Care must be exercised by senior management to ensure that financial results do not become the organisation's "de facto" purpose. Only in crisis may financial results be regarded as the (short-term) purpose.

The organisation's system picture should be the starting place for management's consideration of the relationship between operational and financial measures.

> *Note: ISO 9004's guidance that "management should plan, male available and control the financial resources necessary to implement and maintain an effective quality management system" should be considered carefully. Nothing should be done that would separate "quality" from "operations".*

7 Product and/or service realisation

7.1 Planning of product/service realisation

Vanguard 9001: The organisation shall plan and manage the end-to-end processes required to create complete customer satisfaction at each point of transaction with the customers. Unless designing a new process, this work should start at 'check'.

In conducting 'check', the organisation shall ensure that:

a) **Managerial roles add value to the work by consistently searching for causes within the organisation's total system which are adversely conditioning capability to completely satisfy the customer by the most efficient means, and to champion action on the system to effect necessary change**
b) **Measures of each end-to-end process' capability to achieve its operational purpose should be maintained over time, owned by the people who do the work and used as the operational guide to change activities in pursuit of improved capability**
c) **All such data should be used for the assessment of management performance**
d) **All such data should be available to internal, second and third party audits**

> *Note: This differs from ISO 9001 in that ISO 9001 again places emphasis on "plan" over "check" and "method" over "measures". However, the case can and should be made that these requirements are consistent with the intent in ISO 9001.*

7.1.1 Introduction

Vanguard 9004 (guidance): The core processes that need to be managed to improve product or service realisation will have been defined in the organisation's quality manual (system picture).

In general it is management's responsibility to manage the system – that will have the greatest bearing on product or service realisation. Managers must ensure that measures of all core processes are in place that will tell all personnel how and how well

the core processes are performing. Methods should always be treated as subordinate to measures, permitting experimentation with method – a central feature of learning and improvement.

All work can be considered as a process, governed by the wider system. Achievement of purpose is governed largely by the system – the way work is designed and managed. Achievement of sustained improvement of performance is conditional upon an informed understanding of the impact of the system on current performance.

Effective management of the organisation as a system requires the interaction of work, processes and system factors be viewed and measured from the perspective of purpose. Purpose is defined at the customer/market interface in terms of the fulfilment of customer demand. The fulfilment of customer demand links operational processes in end-to-end flows from the point of demand to the point of fulfilment, typically across functional interfaces. These end-to-end fulfilment flows constitute the core processes of product/service delivery. Their performance capability is dependent upon the effective integration of several sub or functional processes. The purpose of some organisational processes may be the provision of specialised 'support' to the core fulfilment flows – for example, finance, recruitment, training, facilities, health & safety. The effectiveness of the core flows fulfilling customer demand will be determined by how well they are understood and managed as parts of a system.

> *Note:* *ISO 9004 treats any work as a process. The result could be to define and formalise any activity that is plausibly related to the management system. This can be a cause of waste and may obviate learning and improvement. By contrast, the Vanguard Standards focus on the definition of core processes - those that transact with customers - and support processes - those that provide support to core processes. This focus will help prevent wasteful management of activity as though it is a 'process'.*

7.1.2 Issues to be considered

Vanguard 9004 (guidance): The core, end-to-end, fulfilment flows should be identified as the organisation's operational structure for fulfilment of customer demand. The improvement of their operational capability should be the shared accountability of management, end-to-end.

The processes that provide support to the core processes should be managed and measured in terms of the effectiveness of their support in helping the core flows achieve their purpose.

The system picture should be the basic framework informing thinking and improvement activities throughout the organisation.

Clarification of process flow, end-to-end, is an essential tool in the analysis of the "what and why" of current performance. This, with measures versus purpose, should be regarded as central to understanding and action.

Measures of capability are end of process measures of how well what is important to the customer has been fulfilled. Analysed over time, they should be used to identity predictable and unpredictable causes of variation in performance, enabling appropriate management reaction.

Actions for improvement should be chosen on the basis of prediction of extent of improvement. This can only be achieved by investing time and resources in "check".

7.1.3 Managing processes

7.1.3.1 General

Vanguard 9004 (guidance): In general, the management of processes should begin at 'check' - understanding the 'what and why' of current performance. Only new processes cannot be 'managed' in this way in as much as they have to be set up. However, as soon as any new process is in place it should be measured against purpose and adjusted (method) for improvement.

Measurement versus purpose is the first and most important step in managing processes.

> *Note:* *ISO 9004 advises that an operating plan should be defined for process management and advises that it should include a variety of things that may or may not be relevant to a particular process. By starting management of processes with measurement versus purpose, management will be led to those particular issues that affect performance in the particular circumstances. These and only these things should be managed for improvement (versus measures versus purpose). To follow ISO 9004's guidance could lead to an abundance of waste.*

7.1.3.2 Process inputs, outputs and review

Vanguard 9004 guidance: This clause in ISO 9004 makes the same mistake as discussed above. To define and record, a priori, process inputs is to focus on control rather than learning. To begin instead at measurement versus purpose will lead managers to determine those particular inputs that might require attention.

7.1.3.3 Product/service process validation and change

Vanguard 9004 (guidance): As above, process validation and change should begin with measures versus purpose and purpose should be considered as outside-in, customer terms.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product/service

Vanguard 9001: The organisation shall have processes for understanding what matters to its customers. As well as asking customers directly, the organisation should, as appropriate, understand the nature of demands made upon it from the customers' point of view.

> *Note:*   *This is consistent with ISO 9001, with an emphasis on knowing "what matters" and taking an operational view of the type and frequency of customer demands at the point of transaction with the system.*

Vanguard 9004 (guidance): The organisation should seek to engage the customer in an ongoing exploration of the mutual benefits of their business relationship: how it might be improved, customised or developed to their mutual advantage, or how the organisation might alter its interface to become more customer friendly.   An organisation will want this area of exploration with its customers to embrace strategic issues beyond current products or services, to establish the possibilities for new and innovative products and services.

The organisation should also establish a process to determine that all of the following are addressed when receiving an order from a customer:

a) the completeness of the customer's product and/or service requirements
b) requirements not specified by the customer but necessary for fitness of purpose
c) regulatory or legal requirements related to the product or service
d) requirements related to availability, delivery and support of product or service

7.2.2 Review of requirements related to product/service

Vanguard 9001: This is a constant and specific application of 7.2.1 (identification of customer requirements)

Vanguard 9004 guidance: ISO 9001's requirement for review of product requirements will not be relevant to many organisations.   You may choose to exclude this requirement. First address the question: Does this matter to the customer and if so, how? Secondly, address the question: Do we have, at the point of transaction, the information we need to ensure that customer's demand flows cleanly through our system?

7.2.3 Customer communication

Vanguard 9001: In addition to maintaining the exploration of mutual benefits with the customer (7.2.1), and as an element in making transactions with customers more user friendly, the organisation shall determine appropriate arrangements for communicating with customers.

Vanguard 9004 (guidance): The most efficient and effective method for determining appropriate arrangements for communicating with customers is to understand the type and frequency of demand customers make on the system. Managers should work to the principle of designing against demand. Once more, this is to start at 'check' and will lead to the management of only those things that are appropriate for your circumstances.

7.3 Design and development

7.3.1 Design and development planning

Vanguard 9001: Having listened to and understood what matters to customers (7.2.1) the organisation should design and develop product and/or service processes that ensure value is created for customers against their demands.

Note: By contrast, ISO 9001 has a "plan, make, review" approach. The Vanguard Standard treats process design as integral to product/service design in order to work to a "pull" philosophy.

7.3.1.1 General guidance

Vanguard 9004 (guidance): The organisation shall identify all the resources required (design, manufacturing, assembly, installation, servicing etc…) to create value against customer demand and ensure that they are measured and managed as a seamless (demand, design, development and fulfilment) end-to-end flow.

The design and implementation of all planning /design activities and processes shall be directed at an unambiguous statement of the operational purpose to be achieved.

The **scope of purpose** is primarily determined from an understanding of the customer's nominal value, but may be conditioned by resource/finance availability, considerations of risk, life cycle, safety, dependability, maintenance or disposal.

Process design should be considered as integral to service and/or product design.

> *Note:* ISO 9001 requires design and development planning to include stages of design/development, review and validation activities and assignment of responsibilities. These requirements will not suit all organisation forms and may be excluded or interpreted in a manner that fits particular circumstances.

7.3.2 Design and development inputs

Vanguard 9001: What matters to customers is the primary input into design and development activities. The organisation should ensure that what matters to customers is understood, such that it can be expressed in operational terms.

7.3.2.1 Design and development input & output

Vanguard 9004 (guidance): The organisation should take into account any pertinent legal, regulatory, environmental and health and safety requirements.

When considering the completeness of the design and development inputs the line managers of any end-to-end flow should ensure that all relevant data and information from all the relevant upstream steps in the flow are provided in a timely manner. The purpose of this data provision is to ensure that any design meets the requirements of the key upstream steps in the end-to-end flow.

Design and development inputs should only be considered complete when:

a) all the required inputs have been made available
b) design and development can achieve their purpose 100 % without recourse to redesign and/or redevelopment or any other form of waste
c) all the information is available to ensure that each "next step" in the flow will work 100 % clean

The management of this end-to-end flow shall ensure that all the information and data that is deemed relevant to learning and improvement are built into this flow, and captured for use where this is considered necessary or useful.

> *Note:* Again, ISO 9001 takes a "plan and record" approach rather than an "understand and improve" approach.

7.3.3 Design and development outputs

Vanguard 9001: The output of the design and development process should be in a form that shows capability versus the customers' nominal value (7.3.2). The output should include product/service and process design.

Vanguard 9004 (guidance): The purpose of design and development is to ensure that the output:

a) meets what matters to customers
b) specifies a process for manufacture or service delivery, (assembly/installation/fulfilment) which is only concerned with doing value-work
c) define the characteristics of the product or service that are essential to its safe and proper use

Design and development outputs shall be evaluated against the operational purpose to be achieved. This is the measure of capability.

7.3.4 Design and development review

Vanguard 9001: The methods and measures covered by 7.3.2 and 7.3.3 should be reviewed, if necessary, in stages of development.

Vanguard 9004 (guidance): The requirement to review will be a reflection of the service or product complexity and other issues considered relevant by the organisation's management.

7.3.5 Design and development verification

Vanguard 9004 (guidance): There is nothing to add – this is covered by the clauses above.

7.3.6 Design and development validation

Vanguard 9004 (guidance): There is nothing to add – this is covered by the clauses above.

7.3.7 Control of design and development changes

Vanguard 9001: Any change to design and/or development processes should follow the check-plan-do cycle.

Vanguard 9004 (guidance): As with any process, such changes should be made on the basis of prediction (following the check-plan-do model), accompanied by measures and should take account of all interdependencies known in the system.

>   *Note   The requirement to document changes should only be met where documentation is of value.*

7.4 Purchasing

7.4.1 Purchasing process

Vanguard 9001: The organisation shall, in so far as possible, work with suppliers to develop a mutual perspective of the end-to-end process uniting the organisation and suppliers systems in one unbroken supply chain.

7.4.1.1 Purchasing process

Vanguard 9004 (guidance): The point of transaction between the two systems should be treated as part of the end-to-end flow and should not be managed as a functional interface with arbitrary measures or controls.

The most helpful selection criterion with respect to suppliers is their willingness and ability to work with the organisation to manage and improve the joint process in this manner.

The cost of purchasing shall be determined as a cost to the whole process, not just the price from the supplier.

> *Note:* *ISO 9000's requirement to control purchasing processes and evaluate suppliers should not be used to justify incoming inspection and placing obligations on suppliers to register to ISO 9000.*

The purpose of purchasing is the acquisition of resources required for the achievement of operational purpose.

An organisation's purchasing policy shall be based on the principle of 'best value', not lowest cost.

7.4.2 Purchasing information

Vanguard 9001: Purchasing documents should contain the information required by the supplier to effect what is required.

> *Note:* *Caution should be exercised to avoid an 'internally focused' definition of information.*

Vanguard 9004 (guidance): The organisation should, as needed, ensure that all purchase orders are sufficiently accurate, comprehensive and authorised to trigger an "as specified" delivery.

> *Note:* *ISO 9004 encourages users to think in terms of "approved suppliers". Care should be taken to avoid unnecessary bureaucracy.*

7.4.3 Verification of purchased product

Vanguard 9001: The organisation shall determine suitable arrangements for the verification of supplied products/services as deemed necessary.

> *Note: Care should be taken not to create unnecessary bureaucracy. The control of in-bound goods should only be necessary where the goods are highly critical to quality.*

Vanguard 9004 (guidance): The user should be concerned to avoid over-bureaucratic emphasis on verification of supplied goods. The origins of ISO 9000 resulted in an emphasis on "incoming inspection". This should only be applied where absolutely necessary.

The organisation should design a process of verification of delivery against purchase orders and delivery notes to operate at the point of receipt, so that goods and services are quickly released into the organisation's operations.

Where appropriate, the users of the delivered goods or services should identify, with the supplier, data on product or service performance to be communicated for the purpose of improvement.

7.5 Production and service operations

7.5.1 Control of production and service provision

Vanguard 9001: The organisation shall design production and service operations in accordance with a clear operational definition of purpose and measures by measures appropriate to this purpose.

> *Note: ISO 9001 takes a "plan and control" approach to production and service operations, emphasising specification of product, specifications for doing the work, equipment required to achieve conformity, monitoring and releasing the product or service. This is a manufacturing emphasis and should be considered with caution to avoid unnecessary control. ISO 9000 seeks "proof of planning" whereas Vanguard seeks "proof of learning".*

Vanguard 9004 (guidance): Assuming personnel are appropriately selected and/or trained, documented procedures for the performance of the work shall be required only where the line management identifies that without a written procedure, performance is predictably put at risk, or for health and safety reasons. Operational control should focus on the measurement of processes versus purpose.

7.5.2 Validation of processes for production and service provision

Vanguard 9001: Process validation – determining effectiveness and efficacy – is an integral part of the management system.

> *Note:* ISO 9001 uses this clause to distinguish those processes whose "output cannot be verified". This was to cover things like welding and painting, where working to a detailed procedure is preventative – and the work cannot be satisfactorily inspected. This may be a clause you choose to exclude.

7.5.3 Identification and traceability

Vanguard 9001: The organisation shall create the means for identification and traceability only where this is critical to performance or where the customer requires it.

> *Note:* The fact that ISO 9001 requires identification and traceability is a reflection of its antecedents. Care should be taken to note the words "where appropriate" in this clause.

Vanguard 9004 (guidance): Where identification and traceability are required, care should be taken not to create a separate bureaucracy.

7.5.4 Customer property

Vanguard 9001: Where deemed necessary and appropriate, the organisation should exercise responsibility with customer property.

> *Note:* Care should be taken to avoid unnecessary bureaucracy for "identification, verification, protection and maintenance" of customer property as required by ISO 9001. Common sense should be allowed to prevail.

7.5.5 Preservation of product

Vanguard 9001: The organisation shall manage these matters as part of the process design.

> *Note:* Again, the fact that ISO 9001 requires preservation of product including identification, handling, packaging, storage and protection reflects its antecedents. Care should be taken not to depart from common sense. Care should also be taken to ensure that controls do not themselves become the causes of waste in the processes.

7.6 Control of measuring and monitoring devices

Vanguard 9001: The organisation should ensure the reliability of all measuring devices used to manage the work.

Vanguard 9004 (guidance): The management cycle, check-plan-do, should include identification of measures and/or measuring equipment that are critical to process performance. These should only be defined and established as deemed necessary.

8 Measurement, analysis and improvement

8.1 General

Vanguard 9001: The organisation shall establish and use measures of the system, its core processes and support processes.

> *Note:* *This differs in emphasis from ISO 9001. ISO 9001 requires measures to ensure conformance. We stress measures of capability to be the bedrock for learning and improvement.*

8.1.1 Introduction

Vanguard 9004 (guidance): Achievement of purpose is the focus of all measurement, analysis and improvement. Achievement of purpose is the key responsibility of line management. The role of line management is to establish and maintain measures of achievement of purpose, to continuously analyse the workflow to identify what factors within the wider system are affecting performance and to plan change for improved achievement of purpose.

Measures of capability of the system, its core and support processes should be permanent measures, taken over time to establish capability and predictability. The effectiveness and utility of the measures chosen will be evident from the help they provide to understanding and improving the current flows.

Such measures shall be used as thermostatic indicators that the system has changed for the better or worse. However, they can only act as automatic indicators in this way with the application of control charts.

Without the discipline of measurement an organisation's operational performance, whether manufacturing or service, is at the mercy of opinion.

Measurement is essential to improvement.

An organisation can only maintain continuous improvement when all decision making is data based.

> *Note:* *Caution should be exercised against setting arbitrary targets.*

8.1.2 Issues to be considered

Knowledge is distinct from opinion. In organisations, decisions based on opinion are at risk. Sound management depends upon <u>taking the right measures and using them in the right way.</u>

The right measures are always related to achievement of purpose; which requires that purpose is clearly understood in operational terms and that the measures of achievement are identified and recorded <u>over time</u>.

Since purpose is established at the point of transaction with the customer, measures of achievement relate to the <u>capability of end-to-end processes to fulfil customer demand</u>. For support processes, measures of achievement relate to their capability to fulfil the operational needs of the end-to-end processes.

The right use of measures of achievement is dependent upon an appreciation of the <u>theory of variation</u> related to work performance. Variation in performance is the greatest single source of guidance of change to improve capability to achieve purpose.

Measures of capability, <u>taken over time</u>, clarify the lessons to be learnt from current variation in performance. They enable managers to make informed decisions about what to address and what to ignore, to prioritise and validate change with greater confidence and effectiveness than reliance on the more usual tabular data can possibly do.

Putting in place a framework of capability measures across all operational activity within the organisation is the third element of management's responsibility - establishing clear operational purpose, experimenting with method and using measures of capability.

In designing, managing, prioritising and improving, a disciplined use of measures is the only safeguard against vagaries of opinion.

Without measures related to purpose, an organisation cannot <u>know</u> how predictable it is at fulfilling customer demand.

Without measures related to purpose an organisation cannot <u>know</u> how predictable is the customer experience of doing business with it.

Without measures an organisation cannot <u>know</u> how efficient it is, nor how effective its change initiatives are for improved performance.

It is the responsibility of senior management/leadership to ensure that the identification and use of measures related to purpose is a discipline of management practice throughout the organisation. The accountability of managers of differing functional steps in each end-to-end fulfilment flow should be clearly aligned towards the improvement of its overall capability to deliver the customer's nominal value.

Within the framework of capability, measures of current performance (how many, how often?) can help analysis, planning and prioritising change or action on the system. Such <u>within-process measures</u> of performance are frequently temporary, useful as they develop understanding and inform decisions for action.

> *Note:* *ISO 9004 promotes benchmarking as an improvement tool. The only benchmark should be perfection of the process or system. Perfection can only be understood through managing the organisation as a system. Caution should be taken not to participate in benchmarking activity that is nothing more than industrial tourism and/or copying. The first step in benchmarking, if undertaken, should be to understand the "what and why" of current performance of your own system or process. That work usually exposes substantial scope for action for improvement.*

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Vanguard 9001: The organisation shall use measures that give information about what matters to customers. The nature and use of these measures shall be defined.

> *Note:* *This is merely a change of wording to "what matters" as compared to "perception". Consideration of "what matters" leads to other useful data about customers, for example the nature and predictability of customer demands – both "value" and "failure".*

Vanguard 9004 (guidance): Customer measures should be among the system's permanent measures of capability. Quality is a stamp of approval that only the customer can award. Customer satisfaction is one of the three primary measures of an organisation's competence.

The organisation should establish the effectiveness with which it engages its customers in understanding customers' current and future "nominal values" and employs the customers' nominal values as the operational goals.

Every point of transaction with customers is a potential source of learning about how successfully the customers' nominal value(s) is/are being understood and fulfilled.

The utility and impact of customer satisfaction data is conditioned by three variables:

♦ who conducts the exercise of gathering the data

♦ who designs the items which structure any instruments used

♦ how effectively the data are used to improve fulfilment of nominal value

Consideration should be given to each of these issues in the design and implementation of methods to measure and learn from what matters to customers.

Measures of customer satisfaction are measures of capability. Measures of capability should be concerned with both demand – the nature and frequency of customer demands on the system and satisfaction – the value created for customers by the system.

8.2.2 Internal audit

Vanguard 9001: The organisation shall choose how best to carry out internal audits, stating the purpose and methods for the audit process.

> *Note:* *This differs from the requirements of ISO 9001, which are to establish internal audits for the purpose of determining compliance. ISO 9001 makes auditing for improvement optional. Further, ISO 9001 requires that audits are performed by independent parties.*

Vanguard 9004 (guidance): The purpose of internal audit should be to assess whether the factors which condition current performance are being researched and understood, that appropriate change is, or is being, planned to improve performance with respect to understanding customers and achievement of purpose. In this way, audit can be a learning opportunity for managers and workers alike.

Internal audit should follow the same check-plan-do cycle as line management. By focusing on the model of purpose/measures/method, objectivity is safeguarded; capability measures and the use of (temporary) in-process measurement will establish the truth about what is known and being managed.

Should the organisation choose to conform to ISO 9001's requirement for independent audit (using personnel other than those who perform the work), the audit process should conform to the same model: purpose/measures/method and be conducted as a support to line management's responsibility for improved performance.

Auditors must have at least a basic appreciation of organisations as systems, together with an understanding of the theory of variation, the role of measurement in performance improvement and the nature of incentives in relation to intrinsic motivation.

8.2.3 Monitoring and measurement of processes

Vanguard 9001: The organisation shall use measures for the management of core and support processes.

Note: This is consistent with ISO 9001.

Vanguard 9004 (guidance): The organisation should use appropriate process measures. They should be related to purpose, they should help people understand and improve performance.

For managers to measure and monitor processes effectively they must have at least a basic appreciation of their organisation as a system, together with an understanding of the theory of variation, the role of measurement in performance improvement and the nature of incentives in relation to intrinsic motivation.

Viewing their operation from the outside-in positions their understanding that <u>purpose</u> is established at the point of transaction with the customer, its fulfilment is the <u>measure</u> of effectiveness and <u>method</u> (how it is fulfilled) is the operational context of efficiency.

Note: ISO 9004 encourages the use of utilisation measures in measuring process efficiency. Where efficiency measures are not end-to-end measures, care should be taken to prevent action on such measures from causing waste.

8.2.4 Monitoring and measurement of product

Vanguard 9001: The organisation shall use measures for the management of product and service(s) as appropriate.

Note: This differs from ISO 9001 in as much as ISO 9001 requires "verification" that product or service "characteristics" are met. ISO 9001 also requires "records" showing evidence of "conformance" and "indications" of authority for the release of product. These requirements may be of limited value in some organisations, but could create unnecessary bureaucracy in many.

Vanguard 9004 (guidance): The organisation should maintain ongoing measures of capability to deliver product and/or service to the requirements of the customer.

Capability measures of product and/or service delivered, established by reference to what matters to customers are a permanent requirement of line management as this represents the organisation's quality management system.

If customers and/or statutory authorities require, the organisation should be able to indicate where inspection or test points are located in the process with respect to characteristics, verification, having been witnessed, or where, when and how qualified third party testing or validation to be carried out

Note: *By contrast, ISO 9004 takes an "inspection, test, conformance"
approach to product/service measurement. In many circumstances
this can be inappropriate and can lead to unnecessary bureaucracy.*

8.3 Control of nonconforming product/service

**Vanguard 9001: The organisation shall ensure that any person who sees failure
of any kind is able to make the failure visible.**

Note: *ISO 9001 requires the identification, recording and reviewing of non-
conformances. This is a "bomb factory" mentality and has limited
utility. Care should be taken to avoid counter-productive
bureaucracy.*

Vanguard 9004 (guidance): Processes for recording and reviewing non-conformances
should only be defined and established as deemed necessary. In the event of any failure,
the priority for all personnel should be to stop and look – to observe the facts. The facts
should lead to hypotheses for action. Care should be taken to establish common versus
special cause prior to choosing a course of action (if any).

Within an operational culture focused on the improvement of fulfilment processes to
deliver the customer's nominal value, everyone has the authority/responsibility to
identify system factors which are causing failure to fulfil the customer's nominal and/or
causing costs to the organisation.

8.4 Analysis of data

**Vanguard 9001: Measures of the system shall be established such that the
"what and why" of performance of the system, its core and support processes
are the focus for all improvement work.**

Note: *ISO 9001 requires a 'system level procedure' for the analysis of data.
Care should be taken to avoid separating decision-making from work
– this would be (and would create more) waste.*

Vanguard 9004 (guidance): The measure of sustained improvement is the evidence of
the effectiveness of line management as the quality management system. All the
measures mentioned above are the evidence of effectiveness (8.2.1 ; 8.2.1.1 ; 8.2.2) The
analysis of this data is the role of line management, together with the planning of
appropriate change to method and the continuation of measurement to demonstrate the
planned improvement.

An organisation's integrating focus for all its activities is the improvement of its capability to understand and consistently deliver nominal value at the point of transaction with the customer.

The causes of variation in performance lie in the system. The role of management, in conjunction with those they lead, is to analyse (understand) the system to identify the causes of variation and to take action to minimise or remove the causes. The causes of variation may range from lack of understanding of the customer's nominal value, through the design of the work or the work processes, through the measures in use and/or how they are used, to the most basic of all factors – the paradigms which condition the assumptions managers themselves have about good management practice. In-process measures of inefficiency and end of process measures of capability are the objective measures of changes implemented.

Improving capability to deliver the nominal value with improved efficiency is the requirement of all other forms of measurement; customer satisfaction, satisfaction of owners and other interested parties, market and financial interests.

8.5 Improvement

8.5.1 Continual improvement

Vanguard 9001: The organisation should show evidence of continually improved performance.

> *Note:* *That ISO 9001 has a separate clause on improvement is to misunderstand quality. If improvement is not an automatic outcome, the system has not been designed correctly. Improvement is a consequence, not a feature.*

Vanguard 9004 (guidance): An organisation's quality management system is the line management of the organisation, with clarity of operational purpose, operational measures, research and planned change to current methods as the elements of its pursuit of improved performance. It is the quality policy in operation. The organisation shall not create the illusion within its staff that quality is anything other than the way the work is currently done and/or improved and the way the resultant product and/or service is perceived by the customer. Quality is nothing other than the customer's stamp of approval on the organisation's technical and managerial competence. If clauses 1.1 through 8.4 are implemented from a system perspective, this will happen automatically.

The managerial role is to add value to the doing of the work. Understanding and improving performance capability is the essence of the managerial role, providing the required foundation for work design and incentives based on the principles of intrinsic motivation, which are themselves work and achievement based.

8.5.2 Corrective action

Vanguard 9001: The organisation shall develop methods for the reduction of all forms of waste.

> *Note:* *ISO 9001 requires a process for reducing non-conformity. This is only one form of waste and has relevance only to some organisations. Once again, care should be taken to avoid the waste associated with bureaucratic approaches.*

Vanguard 9004 (guidance): Corrective action is the nature of management's planned change in the light of what the measures and investigation of current performance reveals, to eliminate the causes of variation in performance and establish reliably improved achievement of purpose.

All the previous clauses in the standard have contributed to the illustration of this core philosophical principle, with the retention of appropriate documentation to give evidence of its effective implementation.

Capacity is a combination of work and waste. To improve capacity, one must reduce waste of all forms, not just service or product non-conformance. The cycle of check-plan-do is the cycle of corrective action.

8.5.3 Preventive action

Vanguard 9001: The organisation shall develop methods for the reduction of all forms of waste.

> *Note:* *From a systems perspective there is no distinction between corrective and preventative action. ISO 9001 requires a process for the elimination of "potential" non-conformities and their causes. Care should be taken to avoid over-complexity and over-control of processes through "just-in-case" thinking.*

Vanguard 9004 (guidance): Managers who are in touch with the "what and why" of current performance are best positioned to anticipate potential non-conformities and to take appropriate action.

When the causes of unacceptable performance have been identified and a change planned, the new method should be tested against measures.

The cycle of check-plan-do is equally the cycle of preventative action. Measures of capability will help managers and workers decide when and where an early warning indicator might be required: and perhaps, more importantly, when not.

Understanding the causes of variation in performance may lead to redesign of work or process. Only when the requirements for efficient performance are understood should the work or process be redesigned.

8.5.4 Continual improvement of the organisation

Vanguard 9004 (guidance): Continuous improvement will be achieved by managing the organisation as a system.

> *Note:* *ISO 9004 suggests management should create a culture of improvement and suggests this can be achieved by objective-setting, projects, benchmarking, recognition and reward and suggestion schemes. Whilst well-intended, such interventions often reinforce the wrong (command and control) culture. The most effective means for establishing a quality culture are the design and management of work.*