

**The ultimate SME
implementation guide
for
ISO 9001:2000
ISO 14001:2004
management systems**

**Section 2
ISO 9001:2000
Version 2005**



2.1 The implementation of ISO 9001:2000

Fast-Track



There is no quick step-by-step implementation method for a QMS according to ISO 9001 or to any other serious standard. Many have publicised it, but there are too many steps to do and to go through thoroughly making the implementation process complicated. In this approach we claim that all the really needed elements are discussed. What is not needed is not discussed.

The implementation of a formal management system is best handled as a specific project with a professional project manager, who should be a key member of the organisation's management team and having sufficient authority and trust of the personnel involved. In the ideal situation this person will also be the Management Representative, but skills in project management are essential. It is important that none of the stages in the flow chart are omitted.

The existing system of management and working practices must be known in some detail, before the framework of the formal QMS-documentation can be designed. The system is best designed around existing processes as the development of new systems that require additional resources may simply delay the implementation process.

On the next page the total flow chart for the implementation of the QMS is visualised. On the following pages each step of the implementation process is described and includes check boxes of items that have to be carried out before moving to the next step.

It is advised to get more people involved in decision making and not to leave the decision to move to the next step up to one person only. Everybody involved must feel comfortable that a part is under control and that the organisation is ready to move on.

The total implementation process for QMS takes fourteen steps. Communicate with the employees what has done, what has to be done and when it is expected to be completely implemented. This creates interest and involvement and will speed-up the process of implementation.

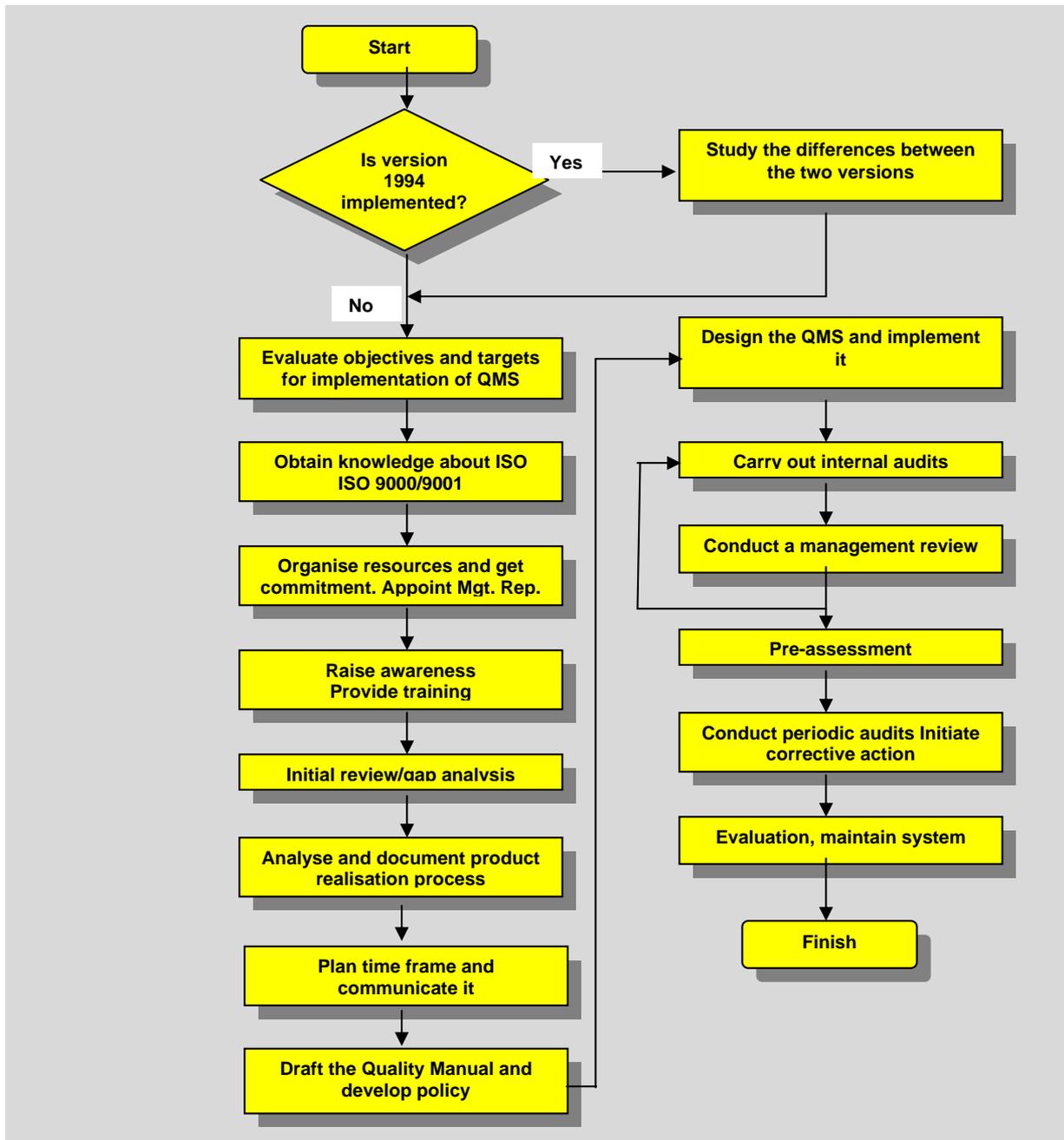


Figure 2.1, The implementation process flow chart

Step 1; Evaluate the organisation's objectives and targets for implementing a QMS.

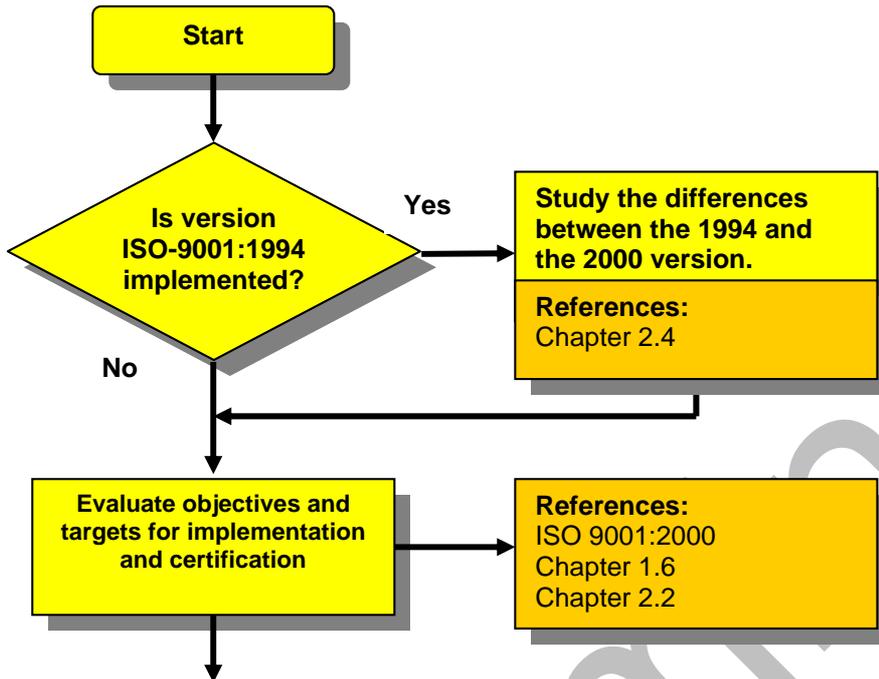
The need for a QMS may arise from repeated customer complaints, frequent warranty returns, delayed deliveries, too high inventories, frequent production hold-ups or a high level of rework or rejection of products or services.

Also it could be that the need for a QMS comes from the market, that is demanding a certified QMS, or otherwise it is impossible to operate in this market, or supply this dominant customer.

Strong technological driven markets such as the aircraft and automotive business, put this demand on their contractors and subcontractors for cost reasons but also for safety and liability reasons.

This third party certification demonstrates the abilities of the SME to the potential customer.

At this stage, identify the goals and objectives which should be achieved through a QMS, such as an improved company structure, greater efficiency, better profitability, reliable supplier etc.



Check on chapter 1.6 for reasoning for the implementation of a Quality Management System.

Introduce the 8 leadership principles to top management and get them motivated and committed to apply to these principles.

Before continuing:



Check that the management has adopted the 8 leadership principles and is motivated and committed to apply them.

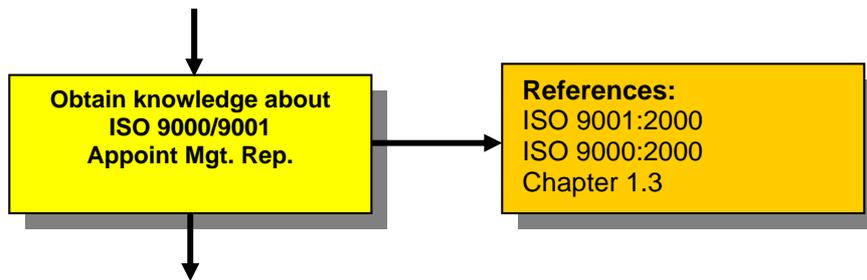


Communicate the objectives and targets for the implementation of the QMS with all the staff.



If there is already a quality system implemented such as ISO 9001:1994, check on the differences and adjust the plan accordingly.

Step 2, Obtain knowledge about the ISO 9000 family and appoint a management representative



Decide on the responsibilities of the person who will be involved in developing and documenting the QMS, including the appointment of a management representative who will oversee the implementation of the QMS. This person does not have to be the same as the implementer

The person made responsible for the process of implementing the QMS should understand the requirements of ISO 9000 and 9001 and read the contents of ISO 9004.

Studying these standards together with this guide will supply sufficient information about the process of implementation of a QMS according to ISO 9000:2000.

Before continuing:

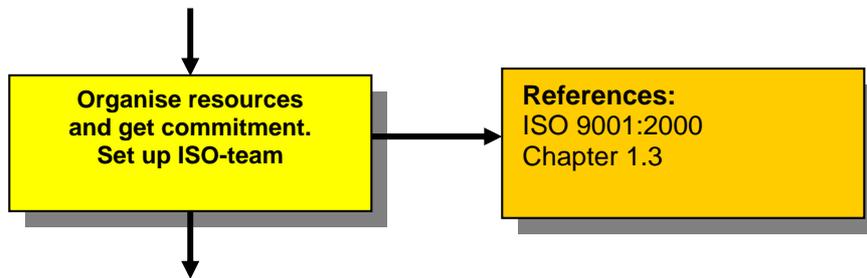


Check to see that the management representative should has been appointed at this stage.



Check that the contents and the philosophy of ISO 9000 and 9001 have been made clear and have been accepted.

Step 3. Organise the resources



Decide on the responsibilities of the person who will be involved in developing and documenting the QMS, including the appointment of a management representative who will oversee the implementation of the QMS. This person does not have to be the same as the implementer. Establishing a project or ISO-team may also prove to be useful to oversee progress and in providing resources wherever required. The ISO-team should consist of involved employees from different levels. Some authority can be given by top management to speed up the process.

If within the organisation no adequate competence is available, or no resources such as time and knowledge can be made available, then a consultant should be appointed.

Before doing so, it is good to realise that with subcontracting a part of the implementation process, a part of the knowledge and the commitment is lost. An organisation can learn more and better from its mistakes and own developments, than from just doing what a consultant is recommending.

Carry out a cost-benefit analysis of hiring a consultant and agree on the scope and timeframe.

Prepare a cost estimate and procure and allocate the resources for this project. Raise commitment from the top management.

Before continuing:



Check that the management has decided upon the individual who will develop the QMS and about its authority.



At this stage, check that the supporting ISO-team is established and the objectives for the team should have been made clear.



Check if a consultant should be involved in this project, make sure that a cost benefit analysis has been carried out beforehand and with a positive result.

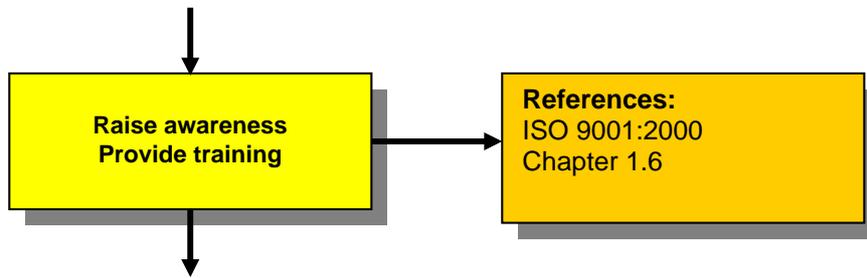


Check if commitment has been made at this stage to the implementation process, if not, it should be stopped here. Don't continue if there is no support group such as an ISO-team or a similar solution.



Check that the needed resources such as manpower, money and time have been made available to the Management Representative and the ISO-team.

Step 4. Raise awareness and provide training



Raise awareness about QMS requirements amongst all personnel performing activities and tasks that affect quality. Plan for and provide specific training on how to develop quality manual, procedures and work instructions. Besides that, it is important to instruct people how to identify and implement improvement processes and how to audit compliance with the QMS.

Appoint a certain number of people to be the internal auditors and provide sufficient training.

The ISO-team and/or the consultant should be resources for assistance during the training.

Before continuing:



Check that training has been provided to the people involved in the writing of procedures and work instructions. Make sure that the written documents reflect the actual situation and not the desired situation.



*Check if a number of people have been selected as internal auditors and that the internal auditor training has been provided.
Many local institutes and certification institutes can help with in-house training.*

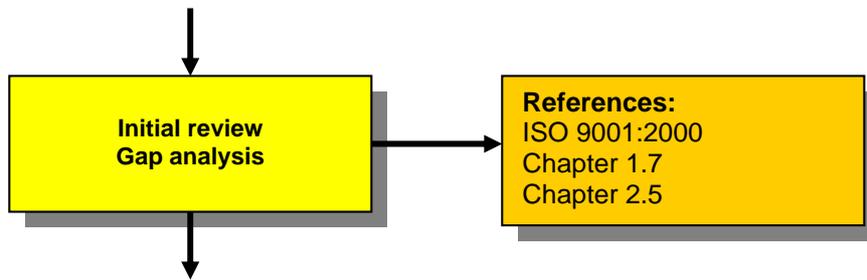


Check that the ISO-team assist in providing insight into the QMS to the other employees by means of presentations, news letters and other ways of communication.



Develop forms that can replace difficult status reporting and provide instruction on how to use them.

Step 5. Initial review / gap analysis



*Evaluate the gaps between the existing QMS and the requirements of ISO 9001:2000.
Prepare how to bridge these gaps, including the planning for any additional resources required.
Gap analysis may be carried out through self-assessment, by the ISO-team or by an external consultant.*

Before continuing:



Check that the gap analysis has been carried out and study the outcome. With this analysis it should be possible to identify the gaps when it is compared with the ISO 9001 QMS

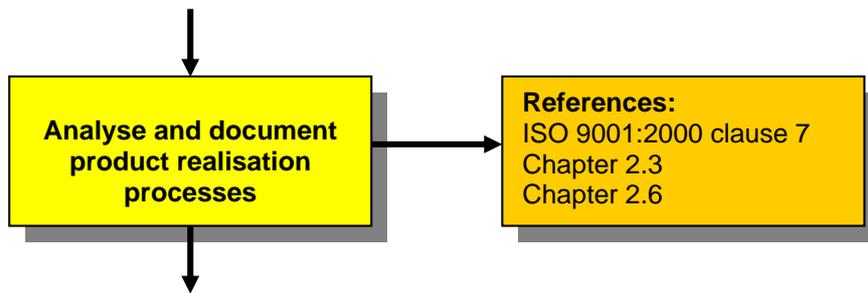


Check that a plan has been developed to bridge the found gaps. Make sure that the plan also contains a time schedule and that the actions are realistic and can be finished in time.



Check that the results of the gap analysis and the actions to bridge the gaps have been reported to top management and that management is also committed.

Step 6. Product realisation processes



Review clause 7 of ISO 9000:2000 relating to Product Realisation to determine how the requirements apply or do not apply to the company's QMS.

The processes covered by this clause include:

- *Customer related processes.*
- *Design and development.*
- *Purchasing.*
- *Production and service provision.*
- *Control of measuring and monitoring devices.*

Note that if the company is not responsible for preparing the design of the product, it can exclude the requirement for design and development from the QMS, as long as the reasoning is mentioned in the quality manual.

Flow chart each process in detail and discuss these flowcharts with the experts, in other words, the people that work with these processes. Draft the framework of the quality management system and identify the supporting documents. Then develop the QMS documentation.

Before continuing:

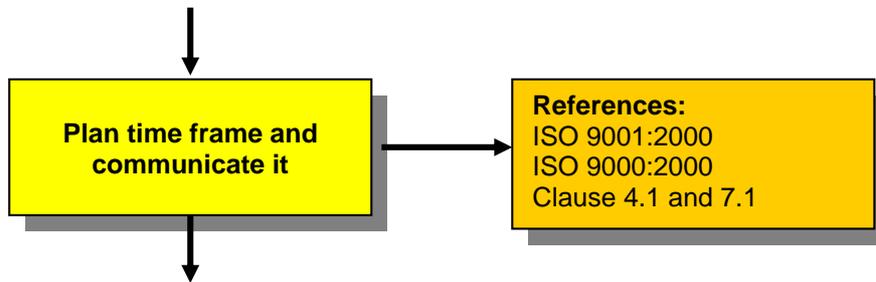


Check to see that all the processes have been properly documented. Have this documentation done by the experts, the people that are responsible for these processes.



Check on the requirements of the standard and exclude the elements that are not applicable to the organisation. Get the approval from top management for these exclusions.

Step 7. Planning and time frame



In this stage the allocation of the resources for the QMS project should be defined. Prepare a complete plan including the plan to close the gaps identified in step 5, to develop the QMS processes.

In the plan, include activities to be performed, resources required, responsibilities and an estimated completion time for each activity. Build in check point to assure in time completion.

Clause 4.1 and 7.1 of ISO 9000:2000 provide information that should be used when developing the plan.

The total time required for each phase (planning, documentation, implementation and evaluation) depends on the extent of the gaps in the existing QMS.

Communicate the master plan to all staff, but especially the ISO-team and the people involved.

Before continuing:

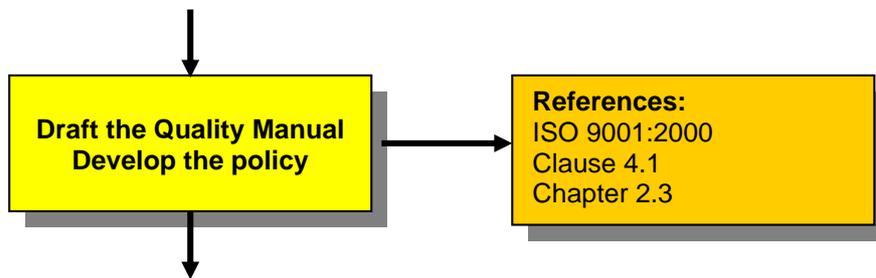


Check that the plan is complete, including the actions to bridge the gaps, a time schedule and the allocation of the resources such as manpower, money and time.



Check that enough effort has been made to communicate the plan and the result of it to all staff. If needed provide extra information to key people and the ISO-team.

Step 8. Draft a quality manual. Develop the policy



In the quality manual:

- *Include how the QMS applies to the products, processes, locations and departments of the organisation.*
- *Exclude any requirement with justification if applicable so as decided in step 6. (Chapter 2.3)*
- *Refer to or include documented procedures (if available already) for QMS.*
- *Describe the interaction between the processes of the QMS, e.g. the interaction between product realisation processes and other management, measurement and improvement processes.*

Draft the quality policy for the organisation. Get the policy committed by top management.

Make sure that the policy is a strong statement, original and applies to the organisation.

Before continuing:



Check that there is an adequate policy developed, that top management is committed and it is a strong statement. Do not continue without this policy statement.



Check that everybody in the organisation has seen it, understands it and can repeat it in his/her own words.



Check that the QMS manual is ready. Don't continue without an approved manual.

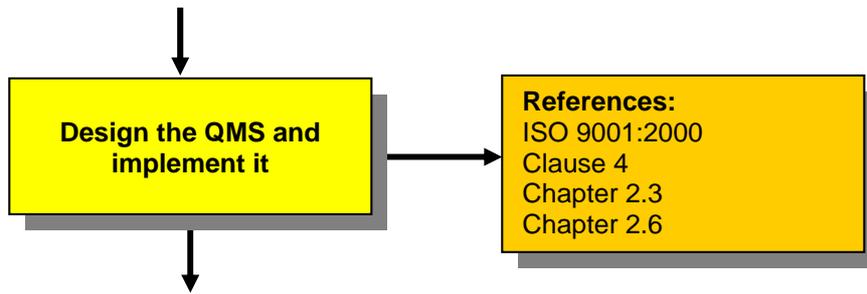


Check that the requirements from the standards are fulfilled and that reference is made to at least six procedures, but no more than that are needed. Keep it simple.



If there is still not sufficient commitment from top management, don't continue.

Step 9. Design the QMS and implement it. Draft the documentation.



The implementation has two parts. The implementation of the QMS, and that of the supporting paperwork.

The implementation of the QMS is another way of working. Define the structure and get the people involved committed to work accordingly.

Introduce the quality manual to the top management. Explain the document structure and how it fits in the QMS.

After top management introduction, middle management should be made aware of the document structure. Top management should be showing that they are working according to the leadership principles.

After company wide commitment, procedures have to be written. ISO 9000 outlines clearly what has to be documented. What is not needed can be decided by the organisation. In principle the employees that work with the documents must write these procedures. The procedures should reflect the actual situation, not the desired one.

After the completion and implementation of the procedures, the next level will be the work instructions.

Here the same system applies. Get the experts to describe their work and activities.

Finally a complete documentation set should be available. It should be noted that only six procedures are required by the standard. Key is that the people involved, work according to these documents.

Maintain the QMS for three months before internal auditing should take place. Correct the QMS where needed.

Before continuing:



Check that the elements of the standards are implemented in the organisation. Elements, such as continual improvement, leadership principles and customer orientation.

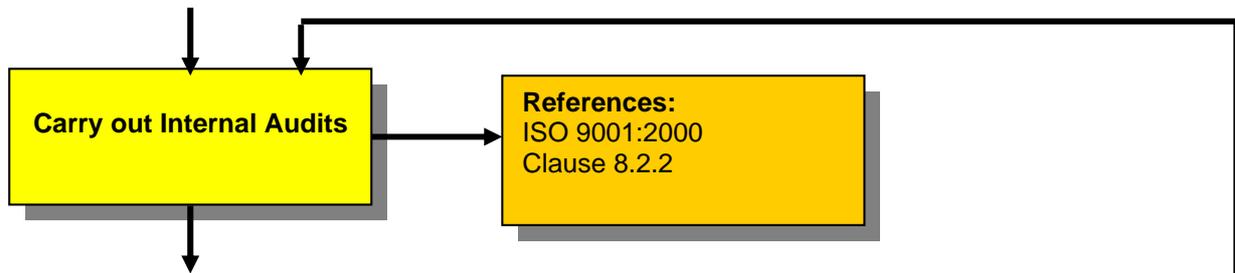


Check that all the needed procedures have been developed and that the work instructions have been written.



Check that the process owners are involved in the development of the work instructions.

Step 10. Carry out internal audits



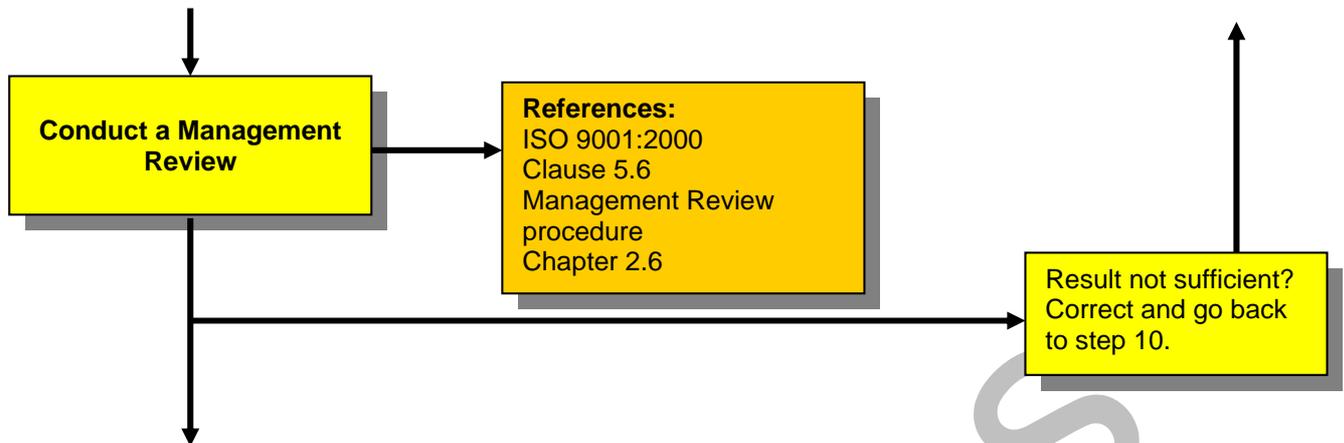
During the phase of implementation of some three to six months after the documentation has been written, the trained auditors should carry out one or two internal audits covering all activities for the QMS, and concerned management should take corrective action on the audit findings without delay. Wherever required, revise the manuals, procedures and objectives. After each internal audit, the top management should review the effectiveness of the system and provide resources for corrective actions and improvements.

Before continuing:

- Check that the responsible people have been trained for the internal auditor function. Record their training results and data.
- Check that internal auditors do not audit their own department or work area.
- Check that the results of the internal audits are fed back into the system and lead to improvement of the QMS, the processes and the documents.
- Check that the results of the internal audits are reviewed on top management level and that appropriate action has been taken.
- Check that there is a time schedule for internal audits and that it is maintained.

Return from step 11

Step 11, Conduct a Management Review



It is important in this stage to have a formal management review that shows the commitment of all levels. The recommendations from this review have to be carried out.

Use the Management Review procedure developed for the organisation.

Before continuing:



Check that the result of the management review is functioning well and that all people involved know what is expected from them. Check the involvement and commitment of the top management. If not sufficient? Go back to step 10.



Check that actions are taken and decisions are made.

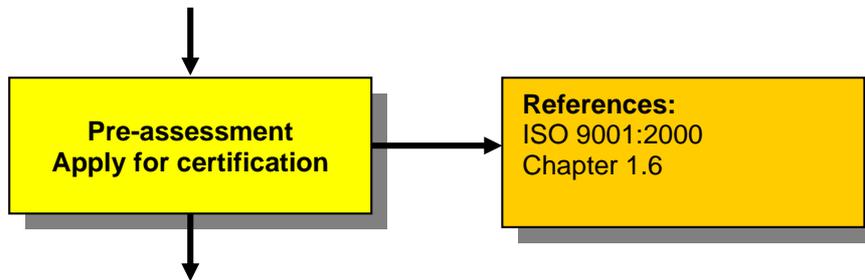


Check that the main focus is on the customer's satisfaction.



Check that the decision makers are present.

Step 12. Pre-assessment. Apply for certification

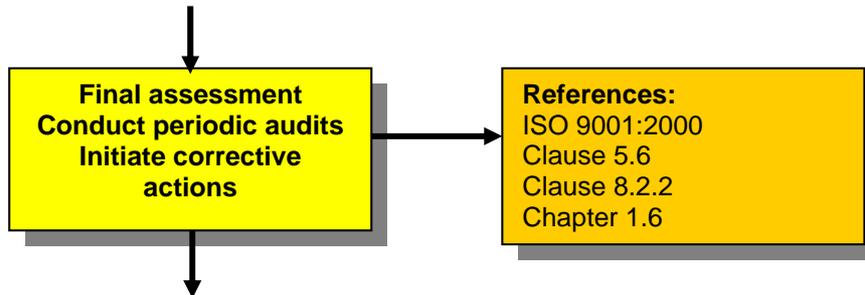


Carry out a pre-assessment. Correct the QMS and the documentation where needed. Re-assessment can be done with the help of an external certification body, but also by local consultants or by consultants from the branch organisation. On satisfactory completion of the previous step, and if the company decided to obtain third party certification, an application for certification should be made to an certification body.

Before continuing:

- Carry out a pre-assessment to win trust and confidence among the people involved in the certification process.*
- Check that actions are taken and decisions are made based on the results of the pre-assessment.*
- Check that the right partner has been found to carry out the pre-assessment.*
- Check that a certification body has been approached for the final assessment. Read the requirements in chapter 1.6 to make sure the right choice has been made.*

Step 13. Conduct periodic evaluations and initiate corrective and preventive actions



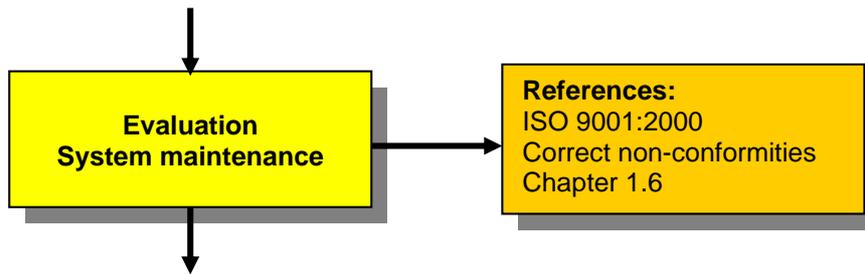
After certification, the organisation should periodically conduct internal audits to review the effectiveness of the QMS and see how it can be continually improved. The organisation should evaluate periodically if the purpose and goals for which the QMS was developed are being achieved, including its continual improvement.

It is needed to look at the organisation's overall systems performance and then decide when and where the most effective improvements can be realised. Then objectives have to be set for those improvements and a periodic evaluation has to be conducted to monitor achievements. Improvements could be the reduction of cycle time within a process or the reduction of contamination in a manufacturing process.

Before continuing:

- Check that periodically internal audits are planned and conducted.
- Check that the non-conformities from the final assessment will be solved as soon as possible.
- Check that the organisation will review its goals and objectives on a regular basis.
- Check that management reviews are planned and conducted periodically.

Step 14. Evaluation



The certification is certainly not the last phase. The people involved need to measure the success of the implementation of the QMS during the implementation process and by the conclusion of the process. Measurements should be made against the original aims and goals and the key indicators of an effective QMS as stated below:

- Check that senior management is fully committed to the QMS and owns the appropriate processes.
- Check that the QMS is designed around business processes and not around ISO 9001 or any other standard.
- Check that staff knows how to access the QMS documentation.
- Check that visibility of processes and the clarity of the instructions in the QMS documentation set are clear, concise, readable and understandable. The people involved maintain their own documents
- Check that the organisational culture is a culture of opportunities, focused around continual improvement rather than a person-to-blame culture.
- Check that the quality management representative is a key organisation person rather than a sideline person.
- Check that internal auditing is seen as adding value and part of the continual improvement of the QMS.



- Continual improvement.
- Keep up with regular internal audits and Management Reviews.

Move on to chapter
2.2, page 21



Quality Management System

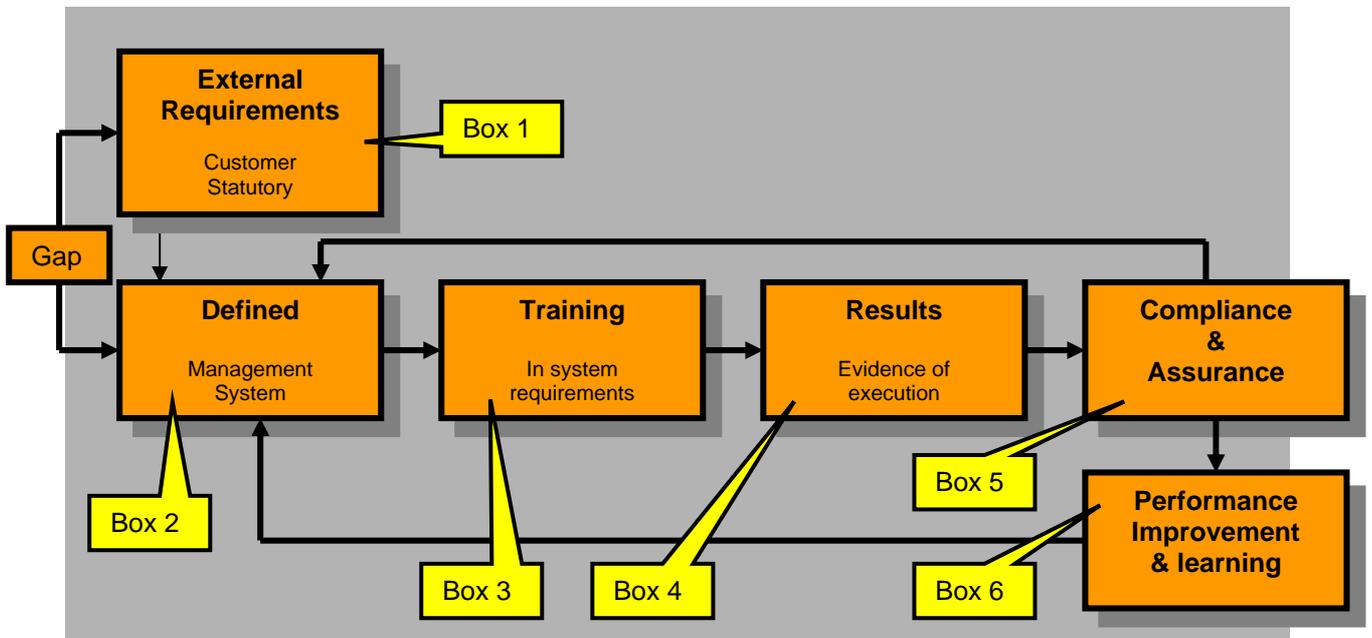


Figure 2.2, The Quality Management System Model

The Quality Management System as shown above, is not complicated and it's clear for each individual involved. The Quality Management System has been developed to:

- Identify all the external quality related input requirements that are specified in regulations, licences, requirements and standards. (box 1)
- Ensure that all these input requirements have been addressed within the management system at the appropriate location in terms of defined specific system requirements. (box 2)
- Ensure that personnel receive applicable training in the system requirements. (box 3)
- Define performance measures applicable to the system requirements.
- Generate the result or evidence that system requirements have been executed (box 4)
- Measure, monitor and report extent of compliance with these performance measures.
- Continually monitor changes to input requirements and ensure that these changes are reflected in changes to the specific system requirements when applicable (box 5)
- Audit and evaluate the system processes and correct them when applicable.
- Provide a culture and process for continually improving the system and feeding back lessons learned in the system. (box 6)

2.2 Structure, scope and application of ISO 9001:2000

ISO 9000:2000 encourages the adoption of the process approach to manage an organisation.

There are five main areas considered for the revised process model in ISO 9000:2000.

- **QMS Quality management system**
- **Management responsibility**
- **Resources management**
- **Product realization**
- **Measurement, analysis and improvement**

QMS quality management system (Clause 4)

This section deals with the general and documentation requirements that are the foundation of the quality management system.

The general requirements are asking to look at the processes of the management system, how they interact with each other, what resources are needed and how to measure and monitor the processes.

The second part of the section then sets out the requirements for the documentation needed, to operate the system effectively and how the documentation should be controlled.

Management responsibility (Clause 5)

The management of the systems is the responsibility of the top management of the organisation, thus at a strategic level. The top management must know customer's requirements, as well as regulatory requirements, at a strategic level and make a commitment to meeting these.

Top management must also set policies; and to achieve these policies, set the objectives plan how the objectives will be met. Top management should also ensure that there are clear internal communications and that the management system is regularly reviewed.

Resource management (Clause 6)

This covers the people and physical resources needed to carry out the process. People should be competent to carry out their tasks, and the physical resources and work environment need to be capable of ensuring that the customer's requirements are met.

Product/service realisation (Clause 7)

These are the processes necessary to produce the product or to provide the service. This is the act of converting the input of the process to the output. For a mining organisation, this may be the process of making magnesium oxide free from its impurities, or processing ore into alumina.

Measurement, analysis and improvement (Clause 8)

These are the measurements to enable the systems to be monitored, to provide information on how the systems are performing related to the customer requirements, the management systems themselves measured through internal audits, the processes and the product measured on their characteristics.

Analysing these, including any defect or shortfall in performance, will provide valuable information for the use in improving the systems and products where this is required.

Each of the five fundamental building blocks is required for any process because, if one is missing, a controlled process does not occur. This is recognised in the new standards and represents a shift to viewing the quality system as a series of processes.

This shift will require an internal or external auditor to look at the organisation's processes and audit them and their output as they occur, rather than audit compliance with the requirements of the previous series of standards.

This new standard will require significant changes in auditing methods for both internal and external auditors.

The process model being used in the standards is fully compatible with the by Dr. Edward Deming developed 'Deming Circle' with the well-known Plan-Do-Check-Act cycle. (PDCA)

Quality management has to include the processes required to achieve quality and highlight their interaction with each other. Top management must take responsibility for leadership, commitment and active involvement for developing and maintaining the quality system. It should provide adequate resources so that customers get what mutually was agreed. It is necessary to have well defined processes, operational and support, to be able to realize the product or service.

Customer satisfaction has to be measured and analysed so that the organisation can be improved continually.

The PDCA cycle is a perfect way for introducing continual improvement. Each step to improve can be defined in the four sub steps, plan, do, check and act.

Plan: *Establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organisation's policy.
To improve the operation by finding what is going wrong (customer complaints, internal complaints, rework etc.) and come up with ideas for solving the problem.*

Do: *Implement the processes
Changes designed to solve the problems are implemented on a small scale to see the effect. This minimises disruption to routine activity while testing whether the changes will work or not.*

Check: *Monitor and measure processes and product against policies, objectives and requirements for the product and report the results.
Whether the small scale is achieving the desired results or not. Also check on key activities to ensure that the quality of the output is conforming and not influenced by the changes.*

Act: *Take actions to continually improve the process performance.
Implement the changes on a larger scale, if the experimental changes have proven to be successful. This means making the changes a routine part of the activity. Also act to involve other people, departments or suppliers affected by the changes and whose co-operation is needed to implement them on a larger scale. Make sure that changes are documented properly according to the documentation requirements.*

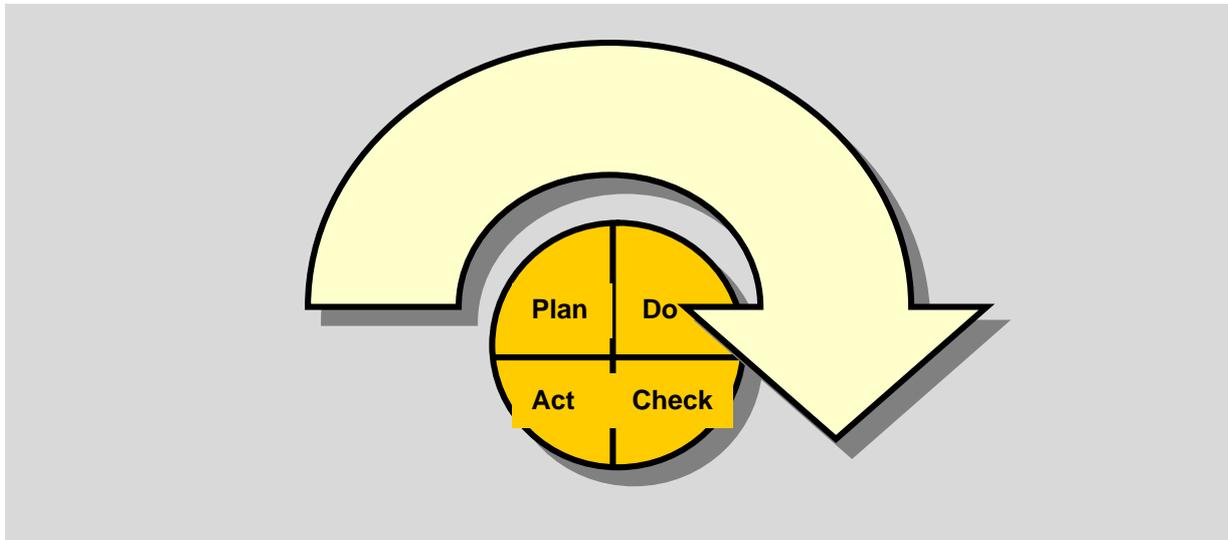


Figure 2.3, the PDCA-cycle



The 8 management principles

ISO 9000:2000 introduces the eight quality management principles on which the quality management system standards of the revised standard series are based.

Top management, as a framework to guide their organisation towards improved performance can use these principles. The principles are derived from collective experience and knowledge of the international experts, who participated in the ISO technical committee that was responsible for developing and maintaining ISO 9000 standards.

The revised standard adopts a process approach in which processes consist of a balance between procedures and competencies.

The eight quality management principles are defined in ISO 9000:2000 and in ISO 9004:2000.

Principle 1, Customer focus

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

Key benefits are:

- Increased revenue and market share obtained through flexible and fast responses to market opportunities.
- Increased effectiveness in the use of the organisation's resources to enhance customer satisfaction.
- Improved customer loyalty leading to repeat business.
- Applying the principle of customer focus, typically leads to researching and understanding customer needs and expectations, but also to ensuring that the objectives of the organisation are linked to customer needs and expectations.

- *Communicating customer needs and expectations throughout the organisation.*
- *Measuring customer satisfaction and acting on the results.*
- *Systematically managing customer relationships.*
- *Ensuring a balanced approach between satisfying customers and other interested parties. (owners, suppliers, employees, financiers etc.)*

Thus, understanding current and future customer needs, meeting current requirements and continuous striving to exceed customer expectations.

Principle 2, Leadership

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

Key benefits are:

- *People will understand and be motivated towards the organisation's goals and objectives.*
- *Activities are evaluated, aligned and implemented in a unified way.*
- *Miscommunication between levels of an organisation will be minimized.*

Applying the principle of leadership should lead to:

- *Considering the needs of all interested parties, including customers, owners, employees, suppliers, financiers and other stakeholders.*
- *Establishing a clear vision of the organisation's future.*
- *Setting challenging goals and targets.*
- *Creating and sustaining shared values, fairness and ethical role models at all levels of the organisation.*
- *Establishing trust and eliminating fear.*
- *Providing people with the required resources, training and freedom to act with responsibility and accountability.*
- *Inspiring, encouraging and recognizing people's contributions.*

Thus establishing unity of purpose, direction and an internal environment where people are fully involved in achieving the organisation's objectives.

Principle 3, Involvement of people

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

Key benefits:

- *Motivated, committed and involved people within the organisation.*
- *Innovation and creativity in furthering the organisation's objectives.*
- *People being accountable for their own performance.*
- *People eager to participate in and contribute to continual improvement.*

Applying the principles of people should lead to:

- *People understanding the importance of their contribution and role in the organisation.*

- *People identifying constraints to their performance.*
- *People accepting ownership of problems and their responsibility for solving them.*
- *People evaluating their performance against their personal goals and objectives.*
- *People actively seeking opportunities to enhance their competence, knowledge and experience.*
- *People freely accepting knowledge and experience.*
- *People openly discussing problems and issues.*

Thus, establishing the full involvement of people and the use of abilities to the organisation's benefit.

Principle 4, Process approach

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

Key benefits:

- *Lower costs and shorter cycle times through effective use of resources.*
- *Improved, consistent and predictable results.*
- *Focused and prioritised improvement opportunities.*

Applying these principle of process approach typically leads to:

- *Systematically defining the activities necessary to obtain desired result.*
- *Establishing clear responsibility and accountability for managing key activities.*
- *Analysing and measuring of the capability of key activities.*
- *Identifying the interfaces of key activities within and between the functions of the organisation.*
- *Focusing on the factors such as resources, methods, and materials that will improve key activities of the organisation.*
- *Evaluating risks, consequences and impacts of activities on customer, suppliers and other interested parties.*

Thus, achieving results in an efficient way by managing related resources and activities as a process.

Principle 5, System approach to management

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

Key benefits:

- *Integration and alignment of the processes that will best achieve the desired results.*
- *Ability to focus effort on the key processes.*
- *Providing confidence to interested parties as to the consistency.*
- *Effectiveness and efficiency of the organisation.*

Applying the principle of system approach to management typically leads to:

- *Structuring a system to achieve the organisation's objectives in the most effective and efficient way.*
- *Understanding the interdependencies between processes of the system.*

- *Structured approaches that harmonize and integrate processes.*
- *Providing a better understanding of the role and responsibilities necessary for achieving common objectives and thereby reducing cross-functional barriers.*
- *Understanding organisational capabilities and establishing resource constraints prior to acting.*
- *Targeting and defining how specific activities within a system should operate.*
- *Continually improving the system through measurement and evaluation.*

Thus, identifying, understanding and managing a system of interrelated processes for a given objective, contributing to the effectiveness and the efficiency of the organisation.

Principle 6, Continual improvement

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

Key benefits:

- *Performance advantage through improved organisational capabilities.*
- *Alignment of improvement activities at all levels to an organisation's strategic intent.*
- *Flexibility to react quickly to opportunities.*

Applying the principle of continual improvement leads typically to:

- *Employing a consistent organisation-wide approach to continual improvement of the organisation's performance.*
- *Providing people with training in the methods and tools of continual improvement.*
- *Making continual improvement of products, processes and systems an objective for every individual in the organisation.*
- *Establishing goals to guide, and measures to track, continual improvement.*
- *Recognizing and acknowledging improvements.*

Thus, continual improvement as a permanent objective.

Principle 7, Factual approach to decision making

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

Key benefits are:

- *Informed decisions*
- *An increased ability to demonstrate the effectiveness of past decisions through reference to factual records.*
- *Increased ability to review, challenge and change opinions and decisions.*

Applying the principle of factual approach to decision making typically leads to:

- *Ensuring that data and information are sufficiently accurate and reliable.*
- *Making data accessible to those who need it.*
- *Analysing data and information using valid methods.*
- *Making decisions and taking action based on factual analysis, balanced with experience and intuition.*

Thus, the factual approach to decision-making based on the logical or intuitive analysis of data and information.

Principle 8, Mutually beneficial supplier relationships

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

Key benefits:

- *Increased ability to create value for both parties.*
- *Flexibility and speed of joint responses to changing market or customer needs and expectations.*
- *Optimisation of cost and resources.*

Applying the principle of mutually beneficial; supplier relationships typically leads to:

- *Establishing relationships that balance short term gains with long term considerations.*
- *Pooling of expertise and resources with partners.*
- *Identifying and selecting key suppliers.*
- *Clear and open communication*
- *Sharing information and future plans*
- *Establishing joint development and improvement activities.*
- *Inspiring, encouraging and recognising improvements and achievements by suppliers.*

Thus, the ability of the organisation and its suppliers to create value is enhanced by mutual beneficial relationships.

Move on to chapter
2.3, page 40



Most of the mining branch-specific items will be laid down in the procedures and work instructions. But also in the Quality Manual, certain aspects are branch oriented. These are mainly found in clause 6 to 8. In the explanation of the standard below, text quotes from the original standard are marked in blue.

1. Scope

1.1 General

This international standard specifies requirements for a quality management system where an organisation:

- *needs to demonstrate its ability to consistently provide a product that meets customer and applicable regulatory requirements, and*
- *aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.*

The standard gives a clear indication of its process nature and also that:

- *It is needed to take into account the regulatory requirements applying to the products*
- *It is needed to have processes in place for continual improvement.*

1.2 Application

All requirements of ISO 9001 are generic and are intended to be applicable to all organisations, regardless of type, size and product provided.

Where any requirements of this standard can not be applied, due to the nature of an organisation and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to ISO 9001 are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organisation's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

This clause requires to state clearly if any areas of the standard do not apply to the organisation, together with an explanation of the reason for this exclusion. The standard mentioned specifically that in case of exclusions, the organisation's ability will not be affected to supply a product or service that will meet customer expectations.

2. Normative reference

This clause explains that the definitions of ISO 9000:2000 Quality Management Systems - fundamentals and vocabulary, apply.

3. Terms and Definitions

The three parties involved in the requirements are clearly shown: supplier, organisation and customer.

The terminology has been brought into line with general usage in the industry and commerce.

Supplier → Organisation → Customer

4. Quality Management System

The Quality Management System (QMS) is the means by which the organisation should be managed and controlled. How to do this is entirely up to the top management. However, the system should use processes to achieve this. Those processes consist of a balance between procedures and competencies.

The current systems for control may already have much of the detail that is needed for the revised standard. There is an all embracing requirement to identify the processes, determine their interaction, and ensure that there is enough information to monitor them and to document them where they are needed to maintain control.

A process is described in the standard as a set of interrelated or interacting activities, which transform inputs into outputs. Put more simply they are those chains of activities that take place across an organisation and deliver the organisation's products or services to either internal or external customers.

Processes are what need to be done, which needs to do it and what is the result. Either procedures and/or competencies will support processes. Procedures and other documents, work instructions etc. define how an activity is required to be done.

In the past there has been a perception that the standard requires a detailed description of every activity undertaken by an organisation and this has led to cases of severe over-documentation.

A quality manual is needed. The standard allows flexibility in respect of its status and structure. It can be part of the overall system, and need only contain the scope of the QMS, processes and any related procedures. System processes need to be detailed.

The standard requires control of documents and records per procedure.

4.1 General requirements

The organisation shall establish, document, implement and maintain a QMS and continually improve its effectiveness in accordance with the requirements of ISO-9001.

The standard requires documented statements of a quality policy and quality objectives. These are usually part of the quality manual.

Also a quality manual, the documented procedures, documents needed by the organisation are required to ensure the effective planning, operation and control of its processes and records. This requires that

- *The processes involved are identified.*
- *The sequence of the operations is determined.*
- *It is ensured that the processes are working correctly.*
- *It is ensured that sufficient resources are available for the processes and the monitoring.*
- *Processes are monitored and improved.*

The organisation must identify the processes for the QMS, determine the sequence and interaction of these processes, determine criteria and methods to ensure that the operation is running effectively, ensure the availability of resources, monitor and measure the processes and implement actions needed to achieve results and continual improvement.

4.2 Documentation requirements

4.2.1 General

This clause defines the types of documentation that must be included in the system:

- *Statements of the quality policy (usually part of the Quality manual)*
- *Quality manual (quality management system manual)*
- *Documented procedures as required.*
- *Documents for effective planning, operation and control (work instructions).*
- *Records as required.*

A note in this section acknowledges that the extent of documentation will depend upon the processes and the competence of the personnel.

4.2.2 Quality manual

The organisation shall establish and maintain a quality manual that fulfils the requirements of the standard and includes:

- *The scope of the QMS*
- *The documented procedures for the QMS*
- *Description of the interaction between processes and the QMS*

The scope of the Quality Management System must justify any exclusion including parts of clause 7.

The manual should include details of any of the reasons why one or more clauses of the standard do not apply to the organisation.

4.2.3 Control of documents

Requirements on the control of the documents, part of the QMS are as follows:

- *Documents have to be approved before issuing.*
- *Documents must be reviewed and updated and approved again.*
- *There must be an identification and control system for the use of the latest revision.*
- *The system to ensure that relevant versions are available effectively.*
- *The system to ensure that documents remain legible and readily identifiable.*
- *The system to ensure that documents from e.g. customers are identified and have a controlled distribution.*

Besides this, the system must prevent unintended use of obsolete documents and to apply suitable identification to them, if they are retained for any other purpose.

A procedure to control these actions is mandatory.

Documented procedures are now required only for:

1. *Document control*
2. *Control of quality records*
3. *Internal audits*
4. *Control of non conformity*
5. *Corrective action*
6. *Preventive action*

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. Records shall remain legible, readily identifiable and retrievable.

A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of the records.

Ensure that records are suitably controlled with regard to:

- *Defining what records are required.*
- *How and where they are stored.*
- *Ensuring that they can be retrieved.*
- *Describing the retention time and subsequent disposal.*

A procedure to control these actions is mandatory.

5. Management Responsibility

5.1 Management commitment

It is important to be aware of the role played by the Top Management of the organisation. ISO 9000:2000 section 3.2.7 defines top management as: Person or a group of people who direct and control an organisation at the highest level.

There is a requirement for top management to show a commitment to the development and improvement of the QMS. It can demonstrate its commitment through leadership and active participation.

The top management also needs to ensure that it understands and meets the regulatory and legal requirements with respect to their products and services it supplies.

The organisation has to determine the customer's needs and expectations for their organisation.

This is aimed not only at individual customers, but also at the market in which the organisation operates.

It must be ensured that top management is committed and involved in:

1. *Communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements.*
2. *Establishing the quality policy.*
3. *Ensuring that quality objectives are established.*
4. *Conducting the management reviews.*
5. *Ensuring the availability of resources.*

5.2 Customer focus

Customer needs must be determined and converted into requirements in order to achieve customer satisfaction. Consideration must be given to legal and regulatory requirement.

It must be described how to ensure customer focus. A person could be made available for determining customer requirements and expectations.

5.3 Quality Policy

Top management shall ensure that the quality policy:

- *Is appropriate to the purpose of the organisation.*
- *Includes a commitment to comply with the requirements.*
- *Continually improve the QMS.*
- *Provides a framework for establishing and reviewing quality objectives.*
- *Is communicated and understood in the organisation.*
- *Is reviewed for continual improvement.*

The quality policy must be appropriate to the purpose of the organisation, thus in line with its activities and objectives.

The quality policy must include a commitment from top management to comply with the requirements and to continually improve the effectiveness of the quality management system. This is a top management job and responsibility.

The quality policy must provide a framework for the establishment of quality objectives and the review of them. Also the quality policy must be communicated through the organisation and must be understood. And of course, also the quality policy is subject to review periodically.

5.4 Planning

Objectives are the targets that are set to achieve the policies. To meet the objectives, the actions to be taken should be planned. This clause clarifies the requirement for objectives and includes continual improvement. Planning includes the use of resources, how processes are used, and the requirement to maintain the system whilst the organisation is undergoing change.

5.4.1 Quality objectives

Quality objectives must be established at relevant function levels to provide continual improvement.

It must be ensured that adequate resources are available to achieve the required level of quality.

Quality objectives must be defined, using measurable terms.

5.4.2 Quality management system planning

Top management shall ensure that quality objectives are established at relevant functions and levels within the organisation.

More emphasis on continual improvement and the involvement of top management.

When changes are made to the system, it must be ensured that the integrity of the system is maintained.

5.5 Responsibility, authority and communication

For the management system to operate effectively there is a need for control over how it is administered.

This is achieved through:

- *Responsibility and authority, which includes the communication of responsibility and authority.*
- *A management representative who plays a pivotal role in the running and organising of the system.*
- *Internal communications, covering the need to be managed communication within the organisation.*

5.5.1 Responsibility and authority

Top management shall ensure that the responsibilities and authorities are clearly defined and communicated within the whole organisation.

The key duties of the senior management should be described. Employees at all levels should be made aware to whom they report and who reports to them. They ought to be aware of the general structure of the organisation.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- Ensuring that the processes needed for the QMS are established.
- Reporting to top management on the performance of the QMS.
- Ensuring the promotion and awareness of customer requirements.

It is needed to establish that the processes of the QMS are maintained. Also those areas for improvement are identified. In addition it is needed to promote the awareness of the customer requirements and to ensure that these requirements are communicated to all people that are concerned.

5.5.3 Internal communication

It must be ensured that there is adequate communication between the various levels of staff and between different departments.

5.6 Management review

The need for top management to review the QMS is essential. This is the route for review and action in respect for continual improvement. Management review is one of the vehicles by which top management will become actively involved in the system and demonstrate their commitment and control.

Management reviews shows the inputs and outputs required.

Review input will come from the results of the audits, customer feedback such as customer complaints. Records from the performance of processes, status of corrective actions initiated because of internal or external feedback.

But also by follow-up actions from the previous management reviews and recommendations for improvement.

5.6.1 General

Top management shall review the organisation's QMS at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and the quality objectives.

5.6.2 Review input

The input to the management review consists of:

- Audit results.
- Customer feedback.
- Process performance and conformity.
- Preventive and corrective actions.
- Follow up on management reviews.
- Changes that can affect the QMS.
- Recommendations for improvement.

5.6.3 Review output

The output from the management review must include decisions made and actions taken related to improving the QMS, the product or the product realisation process and related to resources needed.

- *Improvements to the effectiveness of the QMS.*
- *Improvement of the product or service that is supplied.*
- *Resources needs.*

6. Resource Management

The requirements of this clause cover training needs, training itself, infrastructure, and the work environment. There are also requirements dealing with personnel competence and the evaluation of training effectiveness, together with staff awareness of the relevance and importance of their role and how it contributes to the achievement of the organisation's objectives.

The clause requires identifying and providing company infrastructure. There is a need to take into account, the working environment for personnel and product to ensure that the product conforms to customer requirements. With the infrastructure of an organisation, ISO 9001 means the buildings, workspaces, mines, mining pits, process and transportation equipment and the supporting services such as transport for personnel, waste and product, EDP etc.

6.1 Provision of resources

The organisation shall determine and provide the resources needed.

- *To implement the QMS and continually improve its effectiveness.*
- *To enhance customer satisfaction by meeting the requirements of the customer.*

6.2 Human Resources

6.2.1 General

It is the task of the top management to ensure that the staff is competent for their tasks.

6.2.2 Competence, awareness and training

The effectiveness of training must be controlled and established. Therefore the organisation must:

- *Determine the needed competence for personnel performing work affecting quality.*
- *Provide training or provide proper instruction, including safety aspects and risk awareness.*
- *Evaluate the effectiveness of the above on a planned interval.*
- *Ensure the awareness by its personnel of the relevance and importance of their work and how they can contribute to the achievement of the objectives.*
- *Maintain the records of training.*

Safety on the work place must be integrated within this section.

6.3 Infrastructure

All the utilities must be adequate to support the work environment.

Infrastructure is buildings, mines, mining pits, equipment and supported service such as transport.

6.4 Work environment

In this standard a link is made to the safety and health standard by the statement that the organisation shall determine and manage the mining are (work environment) needed to achieve conformity to product requirements. It is needed to identify and manage the work environment to achieve product conformity and customer requirements. This means that

management must create circumstances within the mining area allowing mining product that can fulfil customer requirements (size, weight, composition, contamination level)

7. Product Realisation

Product realisation is the process of making a product and/or delivering a service, in other words the control over the process. This is related to the process of mining, crushing, separation, washing, cleaning, reduction, transportation etc.

7.1 Planning of realisation process

The planning requirements relate to objectives concerning the product, project, or contract. It must be determined what process is required, how it will be controlled for the realisation of the product or service provided. The clause refers to objectives and how the processes will help to meet them. In the sub paragraphs a - d, requirements are laid down for what should be taken into account when planning the processes. Also it must be noted that the requirements of design may be used to develop the processes. All processes within the QMS must be defined. The use of a flow chart will help to identify the different processes.

7.2 Customer related processes

This clause includes specific requirements concerned with taking into account legal and regulatory requirements relating to the product or to the service provided. An implied need is one where the customer does not specify a requirement but the organisation knows that the requirement is needed to satisfy the customer and also comply with regulatory or legal requirements.

7.2.1 Determination of requirements related to the product

The organisation shall determine:

- *Requirements specified by the customer, including the requirements and post delivery actions.*
- *Requirements not stated by the customer but necessary for specified or intended use, where known.*
- *Statutory and regulatory requirements related to the product.*
- *Any additional requirements determined by the organisation.*

The process of mining and its subsequent steps is basically a continuous process. Nevertheless will customers have different requirements with regards to the product requirements that have to be communicated to the people responsible for the realisation of these requirements.

7.2.2 Review of requirements related to the product

The review must be carried before actual shipping of final product takes place. It must ensure that:

- *Product requirements are defined and communicated with the execution.*
- *Differences in contract or requirements are solved.*
- *The organisation is able to meet the requirements of the customer.*

7.2.3 Customer communications

The organisation shall determine and implement effective arrangements for communicating with customers in relation to:

1. *Product information.*
2. *Enquiries, contacts or order handling, including amendments.*
3. *Customer feed back, including customer complaints.*

Because in many case the mined product is deviating from the expected composition, due to contamination or deviating content, it is essential to inform the customer in time and set up arrangements to handle these deviations.

7.3 Design and/or development

This clause provides a comprehensive description of design and/or development requirements.

It covers both design to customer specifications and off-the-shelf designs. It is applicable to design of services, and to design of products as well. It requires planning activities, agreeing on inputs and outputs. The design should be reviewed against the inputs and verified as it progresses.

Once the design is complete, its validation is required to ensure that it meets the input requirements regardless of whether or not the output is a tangible product or a service. Also changes in the design require a control system.

7.3.1 Design and development planning

The organisation shall plan and control the design and development of the product During this phase the organisation shall determine, the design and development stages, the review, verification and validation with regards to design and development and the responsibilities and authority.

In the mining sector these clause should be interpreted as e.g. reducing waste stream and enhancing higher content product, improved weight and size control and reduction of contamination levels.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4)

These inputs shall include:

1. *Functional and performance requirements.*
2. *Applicable statutory and regulatory requirements.*
3. *Where applicable, information derived from previous similar designs.*
4. *Other requirements essential for design and development.*

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enable verification against the design and development input and shall be approved prior to the release.

7.3.4 Design and development review

The formal documented review from the earlier version is replaced by the systematic review. New requirements are set to identify problems and propose follow-up actions and documentation in records.

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

1. *To evaluate the ability of the results of design and development to meet requirements.*
2. *To identify any problems and propose necessary actions.*

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4)

7.3.6 Design and development validation

*Validation is required to ensure that the resulting product meets the requirements for intended use and fitness for purpose.
Preferable this is done in co-operation with the customer.*

7.4 Purchasing

This clause deals with purchasing in relation to the selection of suppliers. It requires exercising control over suppliers in proportion to the effect that a purchased product has upon the final product to the customer.

It is also required to evaluate the suppliers both initially and periodically.

Purchasing information is a requirement as is verification of the purchased product or service.

7.4.1 Purchasing process

The organisation shall ensure that purchased product conforms to specified purchase requirements.

The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product.

The organisation shall evaluate and select suppliers on their ability to supply product in accordance with the organisation's requirements.

Records of this evaluation are subject to the organisation's retention policy.

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased. This includes approvals for procedures, standards, processes and equipment, requirements for qualified personnel and requirements to the QMS.

7.4.3 Verification of purchased product

The organisation shall establish and implement the inspection for ensuring that the purchased product meets the specified requirements.

Where the organisation or its customer intends to perform verification at the supplier's premises, the organisation shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

In this section, requirements are laid down with regards to the control of production (and service provision) and the validation of the processes. Important are the requirements with regards to identification and traceability throughout the whole production process.

7.5.1 Control of production and service provision

The organisation shall plan and carry out production and service provision under controlled conditions. These controlled conditions must include:

- Information that describes product characteristics.
- The availability of the work instructions and CE marking if applicable.
- The use of the right equipment.
- The availability of monitoring and measuring equipment.
- The implementation of release, delivery and post-delivery actions.

7.5.2 Validation of processes for production and service provision

Identify the special processes, ensure that re-validation of the processes is carried out after any change or alteration.

Validation shall demonstrate the ability of these processes to achieve planned results. The organisation shall establish arrangements for these processes including, as applicable:

- Defined criteria for review and approval of the processes.
- Approval of equipment and qualification of personnel.
- Use of specific methods and procedures.
- Requirements for records (see 4.2.4)
- Revalidation.

7.5.3 Identification and traceability

If appropriate, the organisation shall identify the product by suitable means throughout product realisation.

The organisation is also required to identify the product status.

The nature of the mining industry makes it difficult to identify exactly each batch of mined product. But it is essential to develop a system for identification and traceability because of the different content of mined substance and contamination levels. Basically must each batch be identified and its position in the process flow. Proper records contain the actual quality characteristics against customer or process requirements.

7.5.4 Customer property

The organisation must take care for product supplied by the customer. It must identify, verify, protect and safeguard the product.

Lost or damaged product must be reported to the customer.

7.5.5 Preservation of the product

The organisation must preserve the conformity of product during internal processing and delivery to the intended destination (customer). This preservation must include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent part of a product. Attention must be given to mined products that can oxidise, degrade or lose value or contents.

7.6 Control of measuring and monitoring devices

This clause explains the monitoring devices that are used to control processes. It also deals with the validation of software. (see also 7.2.1)

Where necessary to ensure valid results, measuring equipment shall:

- Be calibrated at specified intervals, prior to use.
- Be adjusted as needed.
- Be identified to enable the determination of the calibration status.
- Be safeguarded from adjustments that can influence the measuring results.
- Be protected from damage during handling, maintenance and storage.

8 Measurement Analysis and Improvement

This clause requires planning how to measure and monitor systems, processes and products. It also refers to statistical techniques and focuses on the need for continual improvement.

8.1 General

This clause requires to plan how to measure and monitor systems. It also refers to the statistical techniques that may be used in measurement and monitoring.

8.2 Measurement and Monitoring

The standard contains a customer satisfaction requirement. It is needed to have a way of measuring customer perception of the company and therefore customer confidence. When this information is available, actions for improvement can be considered.

The requirement for internal audits includes a consideration of the results of previous audits. It is made clear that auditors should not audit their own work or work where they have been involved.

Methods should be made available for measuring processes to check that they are capable of ensuring that the product or service meets requirements, both stated and implied.

8.2.1 Customer satisfaction

In this clause requirements are set to measure customer satisfaction and/or dissatisfaction.

The standard contains a customer satisfaction requirement. There must be a way of measuring customer perception of the supplier and thus for customer confidence. When this information is available, actions for improvement can be considered.

The requirement for internal audits includes a consideration of the results of previous audits. It is made clear that auditors should not audit their own work.

Methods should be in place for measuring out processes to check that they are capable of ensuring that the product or service meets the requirements, both stated and implied.

8.2.2 Internal audit

In this clause the requirements are stated with regards of the internal audit. Important is the statement that an audit programme shall be planned, taking into consideration the status and the importance of the processes and areas to be audited as well as the results of the previous audits.

The selection of auditors and the conduct of audits shall ensure objectivity and impartiality of the audit process..

Selecting and training internal auditors are important aspects of the process of implementation the QMS and other management systems. It is essential that the selection of the internal auditors have been done carefully. It is recommended that people be chosen wide a wide spectrum within the company, rather than employing a specific internal audit department.

This will help to create a good understanding of the formal management systems throughout the company, and avoids the impression that internal auditing is a policing activity.

8.2.3 Monitoring and measurement of processes

The organisation shall apply suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods shall demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

This clause allows for the use of statistical techniques used for the control of processes. Certainly within the mining sector, where measuring of process characteristics is difficult because of the nature of the process, reliable statistical techniques should be applied.

8.2.4 Monitoring and measurement of product

The organisation shall monitor and measure the characteristics of the product to verify that the product requirements have been met in accordance with planned arrangements (see 7.1) Evidence of the conformity shall be maintained. Records must indicate the person's authorising release of the product. (see 4.2.1)

This clause allows for the use of statistical techniques used for the control of product. Certainly within the mining sector, where measuring of product characteristics is difficult because of the nature of the process, reliable statistical techniques should be applied.

8.3 Control of non-conforming product

Non-conformity of a product or service is anything that does not conform to what has been specified. The last paragraph of this clause deals with the detection of a non-conformity after the product has been released or delivered.

The organisation shall deal with non-conforming product by one or more of the following ways:

- *By taking action to eliminate the detected non-conformity.*
- *By authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.*
- *By taking action to preclude its original intended use or application.*

This clause requires a procedure.

Within the procedure a process must be described how to handle nonconforming mining products and the use for other purposes or other customers. Corrective action is in this case not relevant.

8.4 Analysis of data

Analysis of data is an important aspect of the system. It requires all the information from the measurement section to be brought together with a view to effecting improvement.

The analysis of data shall provide information relating to:

- *Customer satisfaction (see 8.2.1)*
- *Conformity to product requirements (see 7.2.1)*
- *Characteristics and trends of processes and products including opportunities for preventive action.*
- *Suppliers.*

8.5 Improvement

8.5.1 Continual improvement

The core of the ISO 9001 standard is actually the continual improvement aspect in the QMS. The standard describes this as follows:

The organisation shall continually improve the effectiveness of the quality management system through the effective use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Continual improvement looks for the improvement of the QMS. It requires to plan improvement systems and to take into account many other activities that can be used in the improvement process.

Typically, these will be the results from the data analysis. Corrective action requirements include development of the means to stop a problem to re-occur.

Preventive action requirements include ways to stop a problem arising in the first place.

It is the proactive analysis of the process, whereas corrective action is the reaction to problems when they arise. Preventive action can be achieved by an assignment of the risk of something going wrong.

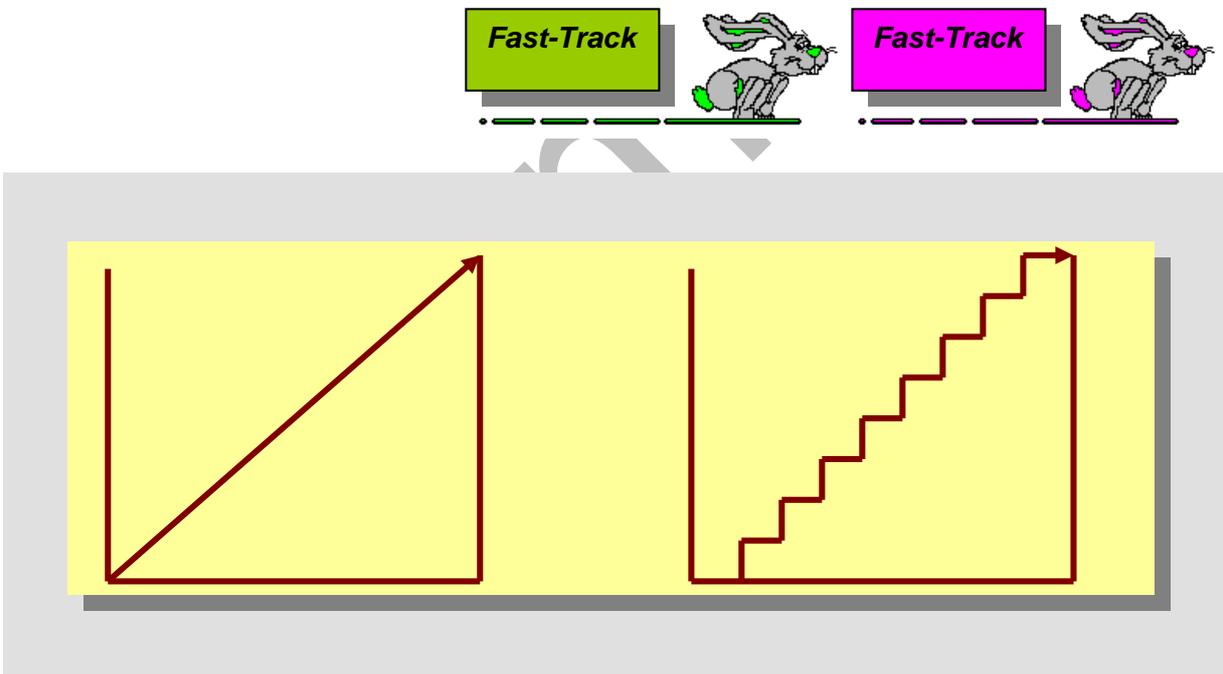
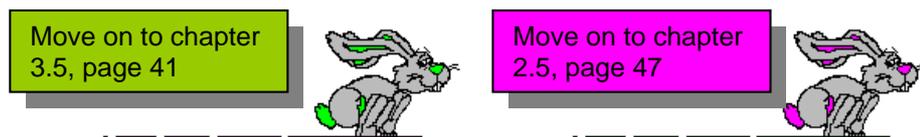


Figure 2.5, Continuous Improvement versus Continual improvement

The above shown diagram, illustrates the differences between Continuous and Continual improvement.

Continual improvement is a step-by-step process of carrying out improvements and then checking to see how effective these steps have been.



8.5.2 Corrective action

The organisation shall take action to eliminate the cause of non-conformities in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the non-conformities encountered.

A documented procedure shall be established to define requirements for:

- *Reviewing non-conformities.*
- *Determining the cause of non-conformities.*
- *Evaluating the need for action to ensure that non-conformities do not occur.*
- *Determining and implementing action needed.*
- *Records of the results of action taken (see 4.2.4)*
- *Reviewing corrective action taken.*

This clause requires a procedure. It is obvious that corrective action is not relevant on the quality of mined substances. To prevent discussions, internal requirements should be set up on such a way that it allows large variation of composition, content or physical properties.

8.5.3 Preventive action

The organisation shall determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effect of the potential problems.

This clause requires a procedure. Here the same comments are valid as mentioned under 8.5.2.

2.4 The differences with ISO 9001:1994

Differences

ISO 9000:2000 has retained a large part of the 1994 version of the standard. Therefore it may not be necessary for a SME that is already certified to any of the three 1994 standards (9001, 9002 or 9003) to change the whole structure of its existing QMS or to rewrite all its procedures.

The most significant is the movement away from a procedurally based approach to management. Instead of stating how activities are controlled, the new standard looks on a process based approach to what is controlled.

The revised standards include many new requirements and changes such as:

- *Increased commitment of top management to the development and improvement of a QMS.*
- *The establishment of measurable quality objectives.*
- *The monitoring of information on customer satisfaction.*
- *a continual improvement process as an important step to enhance the QMS.*
- *The replacement of the artificial 20 elements by 5 broad headings.*
- *The Quality Management System QMS as a concept.*
- *Reinforced focus on resources management.*
- *Activities build around product and services realisation.*
- *A new process oriented structure and a more logical sequence of the contents.*
- *The concept of permissible exclusions to the standard has been introduced with this version, as a way to cope with the wide spectrum of organisations and activities.*
- *The significant reduction in the amount of the required documentation.*
- *Increased compatibility with the EMS standard ISO 14000.*

The SME needs to understand these new requirements, and should consider addressing them in the existing system at the appropriate opportunity.

Benefits

The ISO 9000:2000 series is restructured on a business process model, which more closely corresponds to the way organisations, actually operate and that should result in a QMS that is more effective and easier to use and understand.

The language of the ISO 9000:2000 series has been crafted to make the standards easier to understand and implement by organisations, especially for the SME, where manpower is limited.

The reinforced requirement for customer satisfaction and the inclusion of requirements for monitoring customer satisfaction and for continual improvement, will ensure that user organisations not only do things efficient but also effective.

The ISO 9000:2000 series goes beyond meeting customer requirements to enhancing customer satisfaction. The revised standards can be used as an introduction for achieving Total Quality Management (TQM).

They are based on eight quality management principles, which are discussed in this book in chapter 2.2.

ISO 9001:2000 has been designed to have maximum compatibility with ISO 14000:1996 so that in the future, both systems can be audited at the same time by the same certification body.

ISO 9000:2000 has reduced requirements for documented procedures.

The move towards process management and the removal of the 20 elements from the previous version, will help organisations implement a quality management system that moulds itself to their business, and should avoid the pitfalls of re-designing the business to suit the standard. The emphasis on product or service realisation and customer satisfaction, rather than documentation, is a response on the criticism, that the previous version concentrated too much on documentation and not on the core process of realisation. The need to address continual improvement is something that most responsible organisations have already recognised and this is now an integral part of the standard.

What about the previous version of ISO 9001?

When the three-year transition period expires towards the end of 2003, the 1994 series of standards will be withdrawn, and registration to these standards will no longer be possible and thus the 1994 version certificates will become invalid.

This means that any organisation holding a ISO 9000:1994 series certificate, issued with a National recognised accreditation and who has not updated to ISO 9000:2000, will have its certificate withdrawn.

The replacement of ISO 9002 and 9003 does not mean that SMEs that were certified to these standards have now to demonstrate their capability for 'design and development' of their product which was not covered in ISO 9002, or other requirements such as servicing and purchasing which were not covered in ISO 9003. In fact, the new standard includes a provision allowing companies to exclude certain product realisation processes like design and development, purchasing, customer property, calibration, process validation etc., which were not applicable to them.

SMEs will continue therefore to have the flexibility for implementing ISO 9001:2000 which was earlier possible through the use of ISO 9002 or ISO 9003. SMEs will, however, need to provide justification for exclusion of certain processes and mention that in their system manual.

Conceptual changes

- 1. The most significant is the movement away from a procedurally based approach to management, i.e. stating 'how' the organisation controls its activities, to a 'process' based approach which is more about 'what' the organisation does.*
- 2. The standard is now much simpler in its structure and approach, which makes it easier to use and understand.*
- 3. There is now considerable flexibility within the standard, which requires a balance between documenting an activity and the competence of the staff involved.*
- 4. Its presentation is also different and it introduces certain aspects that were not directly addressed previously.*
- 5. The replacement of the somewhat artificial '20 elements' by 5 broad headings: quality management system; management responsibility; resource management; product/service realisation; measurement, analysis and improvement.*
- 6. 'Continual improvement'*
- 7. The move to 'customer satisfaction' (rather than 'customer complaints')*

The main changes to the standards

The main changes that have been introduced in the 'consistent pair' of Quality Management Systems standards are:

- A new process-oriented structure and a more logical sequence of the contents.
- A continual improvement process as an important step to enhance the quality management system.
- Increased emphasis on the role of top management, which includes its commitment to the development and improvement of the quality management system, consideration of legal and regulatory requirements, and establishment of measurable objectives at relevant functions and levels.
- The concept of 'permissible exclusions' to the Standard has been introduced as a way to cope with the wide spectrum of organisations and activities.
- A requirement for the organisation to monitor information on customer satisfaction and/or dissatisfaction as a measure of system performance.
- Significant reduction in the amount of required documentation.
- Terminology changes/improvements for easier interpretation.
- Increased compatibility with the environmental management system standard.
- Specific reference to quality management principles.
- Consideration of the benefits and needs of all interested parties.

Correspondence between ISO 9001:2000 and ISO 9001:1994

ISO 9001:2000	ISO 9001:1994
1. Scope	1. Scope
1.1 General	
1.2 Application	
2 Normative reference	2. Normative reference
3. Terms & Definitions	3. Definitions
4. Quality Management System	
4.1 General requirements	4.2.1
4.2 Documentation requirements	
4.2.1 General	4.2.2
4.2.2 Quality Manual	4.2.1
4.2.3 Control of Documents	4.5.1
	4.5.2
	4.5.3
4.2.4 Control of records	4.16
5 Management responsibility	
5.1 Management commitment	4.1.1
5.2 Customer focus	4.3.2
5.3 Quality policy	4.1.1
5.4 Planning	
5.4.1 Quality objective	4.1.1
5.4.2 Quality Management system planning	4.2.3
5.5 Responsibility, authority and communication	
5.5.1 Responsibility and authority	4.1.2.1
5.5.2 Management representation	4.1.2.3
5.5.3 Internal communication	
5.6 Management review	

5.6.1 General	4.1.3
5.6.2 Review input	
5.6.3 Review output	
6 Resource Management	
6.1 Provision of resources	4.1.2.2
6.2 Human resources	
6.2.1 General	4.1.2.2
6.2.2 Competence, awareness and training	4.1.8
6.3 Infrastructure	4.9
6.4 Work environment	4.9
7 Product realisation	
7.1 Planning of product realisation	4.2.3 4.10.1
7.2 Customer-related processes (title only)	
7.2.1 Determination of requirements related to the product	4.3.2 4.4.4
7.2.2 Review of requirements related to the product	4.3.2 4.3.3
7.2.3 Customer communication	4.3.4 4.3.2
7.3 Design and development	
7.3.1 Design and development planning	4.4.2
7.3.2 Design and development inputs	4.4.3
7.3.3 Design and development outputs	4.4.4
7.3.4 Design and development review	
7.3.5 Design and development verification	4.4.5
7.3.6 Design and development validation	
7.3.7 Control of design and development changes	4.4.6 4.4.7 4.4.8 4.4.9
7.4 Purchasing	
7.4.1 Purchasing process	4.6.2
7.4.2 Purchasing information	4.6.3
7.4.3 Verification of purchased product	4.6.4 4.10.2
7.5 Production and service provision	
7.5.1 Control of production and service provision	4.9 4.15.6 4.19
7.5.2 Validation of processes for production and service provision	4.9
7.5.3 Identification and traceability	
7.5.4 Customer property	4.8 4.10.5
7.5.5 Preservation of product	4.12

	4.7
	4.15.2
	4.15.3
	4.14.4
	4.15.5
7.6 Control of monitoring and measuring devices	4.11.1
	4.11.2
8 Measurement, analysis and improvement	
8.1 General	4.10.1
	4.20.1
	4.20.2
8.2 Monitoring and measurement	
8.2.1 Customer satisfaction	
8.2.2 Internal audit	4.17
8.2.3 Monitoring and measurement of processes	4.17
	4.20.1
	4.20.2
8.2.4 Monitoring and measurement of product	4.10.2
	4.10.3
	4.10.4
	4.10.5
	4.20.1
	4.20.2
8.3 Control of non-conforming product	4.13.1
	4.13.2
8.4 Analysis of data	
8.5 Improvement	4.20.1
8.5.1 Continual improvement	4.20.2
	4.1.3
8.5.2 Corrective action	
8.5.3 Preventive action	4.14.1
	4.14.2
	4.14.1
	4.14.3

2.5 Gap analysis template ISO 9001:2000

Fast-Track



ISO 9001:2000 Requirements	Status yes/no/none	Action
4. Quality Management System		
4.1 General requirements		
Are processes in place needed for QMS and their application throughout the organisation have been determined?		
Has the sequence and interaction of these processes have been determined?		
Does the criteria and methods needed to ensure both the operation and control of these processes are effective have been determined?		
Does the availability of resources and information needed to support the operation and monitoring of these processes are ensured?		
Are these processes are monitored, measured and analysed?		
Are actions needed to achieve planned results and continual improvement of these processes is implemented?		
4.2 Documentation requirements		
4.2.2 Quality manual		
Has a quality manual been established and is it maintained?		
Does the scope of the manual include details of and justification for any exclusion?		
Does the manual contain or references the documented procedures established for the QMS?		
Does the manual contain a description of the interaction between the processes of the QMS?		
4.2.3 Control of Documents		
Are all QMS documents controlled?		
Is a documented procedure established to define the controls needed to:		
Approve documents for adequacy prior to issue?		
Review and update as needed and re-approve documents?		
Ensure that changes and the current revision status of documents are identified?		
Ensure that relevant versions of applicable documents are available at points of use?		
Ensure that documents remain legible and readily identifiable.		
Ensure that documents of external origin are identified and their distribution controlled?		
Prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose?		
4.2.4 Control of records		
Are records legible, readily identifiable and retrievable?		

Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?		
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5.1 Management commitment		
Does top management communicate the importance of meeting customer, statutory and regulatory requirements?		
Is a quality policy established?		
Are quality objectives established?		

5.2 Customer focus		
Has top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction?		

5.3 Quality policy		
Is the policy appropriate to the purpose of the organisation?		
Does the policy include a commitment to comply with requirements and continually improve the effectiveness of the QMS?		
Does the policy provide a framework for establishing and reviewing quality objectives?		
Is the policy communicated among personnel and understood?		
Is the policy reviewed for continuing suitability?		

5.4 Planning		
5.4.1 Quality objectives		
Are the quality objectives, incl. those needed to meet requirements for product, established at relevant functions and levels within the organisation?		
Are the quality objectives measurable and consistent with the quality policy?		

5.4.2 QMS planning		
Is the QMS planning carried out in order to meet the requirements given in 4.1, as well as the quality objectives?		
Is the integrity of the QMS maintained when changes to the QMS are planned and implemented?		

5.5 Responsibility, authority and communication		
5.5.1 Responsibility and authority		
Are responsibilities and authorities defined and communicated?		

5.5.2 Management representative		
Has top management assigned a Management representative who reports on the performance of the QMS and needs for improvement?		
Does the MR ensure the promotion of awareness of customer requirements throughout the organisation?		

5.5.3 Internal communication		
Is an appropriate communication processes established?		
Is communication taking place regarding the effectiveness of the QMS?		

5.6 Management review		
5.6.1 General		
Does top management reviews the QMS at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?		
Does the review include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives?		
Are the records from management reviews are maintained?		

5.6.2 Review output		
Includes results of audits?		
Includes customer feedback?		
Includes process performance and product conformity?		
Includes status of preventive and corrective actions?		
Includes follow-up actions from previous management reviews?		
Includes changes that could affect the QMS?		
Includes recommendations for improvement?		

5.6.3 Review output		
Includes improvement of the effectiveness of the QMS and its processes?		
Includes improvement of product release to customer requirements?		
Includes resources needed?		

6. Resource management		
6.1 Provision of resources		
Is the organisation determined and provided the resources needed to implement and maintain the QMS and continually improve its effectiveness?		
Is the organisation determined and provided the resources needed to enhance customer satisfaction by meeting customer requirements?		

6.2 Human resources		
6.2.1 General		
Are the personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience?		

6.2.2 Competence, awareness and training		
Are the needed competences of personnel to perform work affecting product quality determined?		
Has training been provided or other actions taken to satisfy these competency/awareness/training needs?		
Has the effectiveness of the actions taken been evaluated?		
Are the personnel aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?		
Are records of education, training, skills and experience maintained?		

6.3 Infrastructure		
Has the organisation determined, provided and maintained the infrastructure needed to achieve conformity to product requirements? (This includes, as applicable, buildings, workspace, equipment and supporting services)		

6.4 Work environment		
Has the organisation determined and manages work environment to achieve conformity to product requirements?		

7. Product realisation		
7.1 Planning of product realisation		
Has the organisation planned and developed the processes needed for product realisation? Is planning of product realisation consistent with the requirements of the other processes of the QMS?		
Is in planning product realisation, the organisation determined to realise the following, as appropriate:		
Quality objectives and requirements for the product?		
The need to establish processes, documents, and provide resources specific to the product?		
Required verification, validation, monitoring, inspection and test activities specific to the product?		
Records needed to provide evidence that the realisation processes and the resulting product meet requirements?		
The output of this planning is in a form suitable for the organisation's method of operation?		

7.2 Customer-related processes		
7.2.1 Determination of requirements related to the product		
Are the requirements specified by the customer, including the requirements for delivery and post-delivery activities determined?		
Are the requirements not stated by the customer but needed for specified or intended use, where known determined?		
Are the statutory and regulatory requirements related to the product determined?		
Are additional requirements determined by the organisation determined?		

7.2.2 Review of requirements related to the product		
Is the organisation reviewing the requirements related to the product?		
Is this review conducted prior to the organisation's commitment to supply a product to the customer? (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders)		
Does the review ensures that:		
Product requirements are defined?		
Contract or order requirements differing from those previously expressed are resolved?		
The organisation has the ability to meet the defined requirements?		
Records of the results of the review and actions arising from the		

review are maintained?		
Where the customer provides no documented statement of requirement, the customer requirements are confirmed by the organisation before acceptance?		
Where product requirements are changed, the organisation ensures that relevant personnel are made aware of the changed requirements?		

7.3.2. Customer communication		
Has the organisation determined and implemented effective arrangements for communicating with customers in relationship to:		
Product information?		
Enquiries, contracts or order handling, including amendments?		
Customer feedback, including customer complaints?		

7.3 Design and development		
7.3.1 Design and development planning		
Does the organisation plans and controls the design and development of product?		
Does during the design and development planning, the organisation determines the:		
Design and development stages?		
Review, verification and validation that are appropriate to each design and development stage?		
Does the organisation manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility?		
Is planning output updated, as appropriate, as the design and development progresses?		

7.3.2 Design and development inputs		
Are inputs relating to product requirements determined and records maintained?		
Does product requirements include:		
Functional and performance requirements?		
Applicable statutory and regulatory requirements?		
Where applicable, information derived from previous similar designs?		
Other requirements essential for design and development?		
Are these inputs reviewed for adequacy? Requirements are complete, unambiguous and not in conflict with each other?		

7.3.3 Design and development outputs		
Are the outputs of design and development provided in a form that enables verification against the design and development input and shall be approved prior to release?		
Do design and development outputs:		
Meet the input requirements for design and development?		
Provide appropriate information for purchasing, production and for service provision?		
Contain or reference product acceptance criteria?		
Specify the characteristics of the product that are essential for its safe and proper use?		

7.3.4 Design and development review		
Are at suitable stages, systematic reviews of design and development performed in accordance with planned arrangements to:		
Evaluate the ability of the results of design and development to meet requirements?		
Identify any problems and propose needed actions?		
Participants in such reviews include representatives of functions concerned with the design and development stages being reviewed?		
Records of the results of the reviews and any needed actions are maintained?		

7.3.5 Design and development verification		
Is verification performed in accordance with planned arrangements to ensure that the design and development outputs met the design and development input requirements?		
Are records of the results of the verification and any needed actions maintained?		

7.3.6 Design and development validation		
Is design and development validation performed in accordance with planned arrangements so that the resulting product is capable of meeting the requirements for the specified application or intended use, where known?		
Wherever practicable, is validation completed prior to the delivery or implementation of the product?		

7.3.7 Control of design and development changes		
Is design and development changes identified and records are maintained?		
Are the changes reviewed, verified and validated, as appropriate, and approved before implementation?		
Is the review of design and development changes included in the effect of changes on constituent parts and product already delivered?		
Are records of the results of the review of changes and any needed actions maintained?		

7.4 Purchasing		
7.4.1 Purchasing process		
Does the organisation ensure that the purchased product conforms to specified purchase requirements?		
Does the type and extent of control applied to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realisation or the final product?		
Does the organisation evaluate and selects suppliers based on their ability to supply product in accordance with the organisation's requirements?		
Are criteria for the selection, evaluation and re-evaluation of suppliers established?		
Are records of the results of evaluations and any needed actions		

arising from the evaluation maintained?		
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7.4.2 Purchasing information		
Does purchasing information describe the product purchased?		
Where appropriate, does purchasing information includes:		
Requirements for approval of product, procedures, processes and equipment?		
Requirements for qualification of personnel?		
QMS requirements?		
Does the organisation ensure the adequacy of specified purchase requirements prior to their communication to the supplier?		

7.4.3 Verification of purchased product		
Has the organisation established and implemented the inspection, or other activities, needed for ensuring that purchased product meets specified purchase requirements?		
When the organisation or its customer intends to perform verification at the supplier's premises, does the organisation states the intended verification arrangements and method of product release in the purchasing information?		

7.5 Production and service provision		
7.5.1 Control of production and service provision		
Does the organisation plans and carries out production and service provision under controlled conditions?		
Does controlled conditions include, as applicable, the:		
Availability of information that described the characteristics of the product?		
Availability of work instructions, as needed?		
Use of suitable equipment?		
Availability and use of monitoring and measuring devices?		
Implementation of monitoring and measurement?		
Implementation of release, delivery and post delivery activities?		

7.5.2 Validation of processes for production and service provision		
Does the organisation validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement?		
Does validation demonstrates the ability of these processes to achieve planned results?		
Has the organisation established arrangements for these processes including, as applicable:		
Defined criteria for review and approval of the processes?		
Approval of equipment and qualification of personnel?		
Use of specific methods and procedures?		
Requirements of records?		
Revalidation?		

7.5.3 Identification and traceability		
Where appropriate, has the organisation identified the product by suitable means throughout product realisation?		
Does the organisation identify the product status with respect to		

monitoring and measurement requirements?		
Where traceability is a requirement, does the organisation controls and records the unique identification of the product?		

7.5.4 Customer property (can include intellectual property)		
Does the organisation exercise care with customer property while it is under the organisation's control or being used by the organisation?		
Does the organisation identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product?		
If any customer property is lost, damaged or otherwise found to be unsuitable for use, is this reported to the customer and records are maintained?		

7.5.5 Preservation of product.		
Does the organisation preserves the conformity of product during internal processing and delivery to the intended destination?		
Does this preservation include identification, handling, packaging, storage and protection?		
Does preservation also applies to the constituent parts of a product?		

7.6 Control of monitoring and measuring devices.		
Does the organisation determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determine requirements?		
Has the organisation established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements?		
Where needed to ensure valid results, is measuring equipment:		
Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to measurement standards?		
Where no such standard exist, the basis used for calibration or verification is recorded?		
Adjusted or re-adjusted as necessary?		
Identified to enable the calibration status to be determined?		
Safeguarded from adjustments that would invalidate the measurement results?		
Protected from damage and deterioration during handling, maintenance and storage?		
Does the organisation assesses and records the validity of the previous measuring results when the equipment is found not conform to requirements?		
Does the organisation take appropriate action on the equipment and product affected?		
Are records of the results of calibration and verification maintained?		
When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed. Is this undertaken prior to initial		

use and reconfirmed as needed?		
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8 Measurement, analysis and improvement		
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8.1 General		
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Does the organisation plans and implements the monitoring, measurement, analysis and improvement processes needed to:		
Demonstrate conformity of the product?		
Ensure conformity of the QMS?		
Continually improve the effectiveness of the QMS?		
Does this include determination of applicable methods, including statistical techniques, and the extent of their use?		

8.2 Monitoring and measurement		
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8.2.1 Customer satisfaction		
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As one of the measurements of performance of the QMS, does the organisation monitors information relating to customer perception as to whether the organisation has met customer requirements?		
Has the method for obtaining and using this information been determined?		

8.2.2. Internal audit		
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Are internal audits conducted at planned intervals?		
Are internal audits determine whether the QMS;		
Conforms to the planned arrangements to requirements of ISO 9001 and to the QMS requirements established by the organisation?		
Is effectively implemented and maintained?		
Is the audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?		
Are the audit criteria, scope, frequency and methods defined?		
Is by the selection of auditors and the conduct of audits ensured objectivity and impartiality of the audit process?		
Do auditors not audit their own work?		
Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records defined in a documented procedure?		
Is ensured that actions are taken undue delay to eliminate detected non-conformities and their causes?		
Are follow-up activities included in the verification of the actions taken and the reporting of verification results?		

8.2.3 Monitoring and measurement process		
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Does the organisation apply suitable methods for monitoring and where applicable, measurement of the QMS processes?		
Are these methods demonstrating the ability of the processes to achieve planned results?		
When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?		

8.2.4 Monitoring and measurement of product		
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Does the organisation monitors and measures the characteristics		
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of the product to verify that product requirements have been met?		
Is this carried out at appropriate stages of the product realisation process in accordance with the planned arrangements?		
Is evidence of conformity with the acceptance criteria is maintained?		
Do records indicate the person(s) authorising product release?		
Do product release and service delivery not proceed until the planned arrangements (7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?		

8.3 Control of non-conforming product		
Does the organisation ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery?		
Are the controls and related responsibilities and authorities for dealing with non-conforming product defined in a documented procedure?		
Does the organisation deals with non-conforming product by one or more of the following ways:		
By taking action to eliminate the detected non-conformity?		
By authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer?		
By taking action to preclude its original intended use of application?		
Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained are maintained?		
Where non-conforming product is corrected is it subject to re-verification to demonstrate conformity to the requirements?		
When non-conforming product is detected after delivery or use has started, does the organisation takes action appropriate to the effects, or potential effects, of the non-conformity?		

8.4 Analysis of data		
The organisation has determined, collected and analysed appropriate data to demonstrate the suitability and effectiveness of the QMS and has evaluated where continual improvement of the effectiveness of the QMS can be made.		
Customer satisfaction (8.2.1)?		
Conformity to product requirements (7.2.1)?		
Characteristics and trends of processes and products including opportunities for preventive action?		
suppliers ?		

8.5 Improvement		
8.5.1 Continual improvement		
Does the organisation continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review?		

8.5.2 Corrective action		
Has the organisation taken action to eliminate the cause of non-		

conformities in order to prevent recurrence?		
Are corrective actions appropriate to the effects of the non-conformities encountered?		
Is a documented procedure established to define requirements for:		
Reviewing non-conformities, including customer complaints?		
Determining the causes of non-conformities?		
Evaluating the need for action to ensure that non-conformities do not recur?		
Determining and implementing action needed?		
Records of the results of action taken?		
Reviewing corrective action taken?		

8.5.3 Preventive action		
Does the organisation determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence?		
Are preventive actions appropriate to the effects of the potential problems?		
Is a documented procedure established to define requirements for:		
Determining potential non-conformities and their causes?		
Evaluating the need for action to prevent occurrence of non-conformities?		
Determining and implementing action needed?		
Records of results of actions taken (4.2.4)?		
Reviewing preventive action taken?		

Move on to chapter
2.6, page 63



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2.6 System documentation ISO 9001

The text part of this chapter applies to both QMS and EMS systems.

The first task is to develop the initial framework of the QMS/EMS, identifying the various processes that are used to deliver the products or services to the (internal or external) customer.

From the framework of the management system the ISO-team will identify the required supporting documentation, firstly in terms of defined processes and then in terms of the competency and procedures that will support these processes.

Once the full framework of the QMS/EMS has been designed and the required documentation identified, it is important to prepare a plan for implementation (see chapter 2.5) so that all participants understand their responsibilities. The plan will detail the authors of the various documents, the personnel responsible for the later stages of the implementation and will include the associated deadline for completion.

Document structure

The document structure of a Quality/Environmental Management System consists of three levels.

Level 1, the top level, describes the Quality/Environmental Management System in accordance with the stated quality policy and with the objectives. The manual references to the management system procedures.

Level 2 contains the QMS/EMS procedures defined by ISO, for compliance with the requirements of the standards. The procedures make reference to the work instructions and forms.

Level 3 consists of detailed work documents and other related documents like forms to document processes.

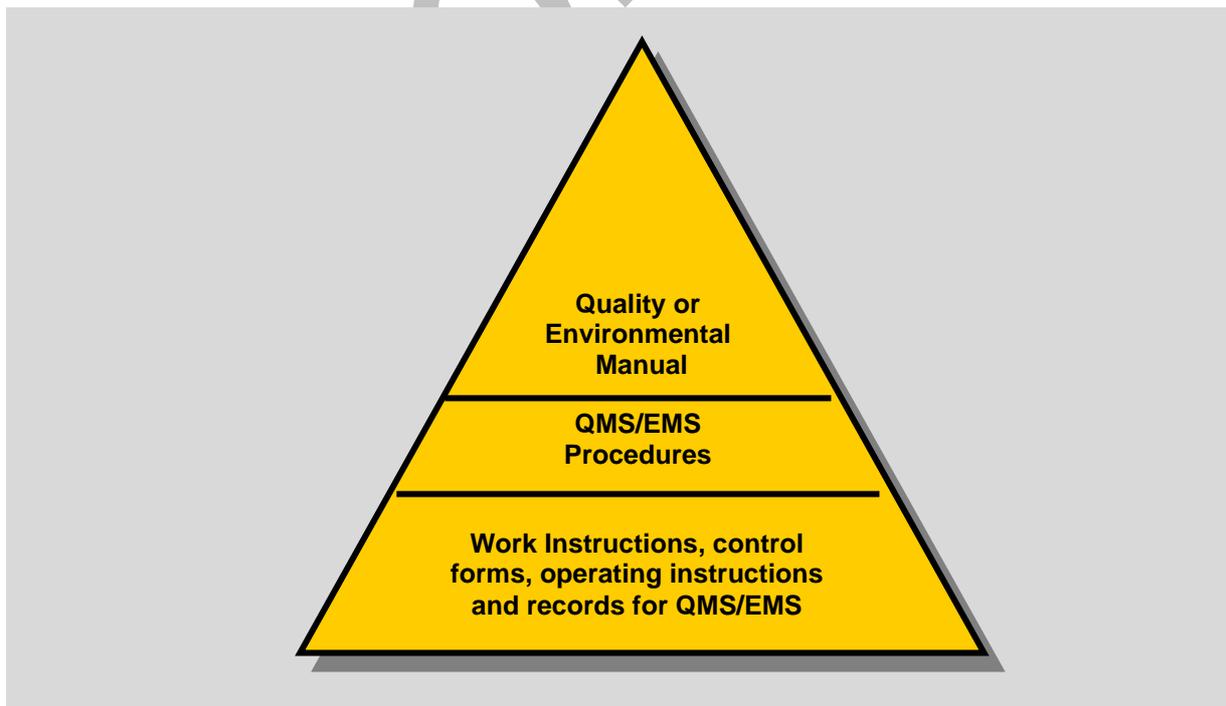


Figure 2.6, the document structure

Management system manual

A management system manual is unique to each organisation. An SME may find it appropriate to include the description of its entire quality/environmental management system within a single manual, including all the documented procedures required by ISO 9001 or ISO 14001.

The management system manual should include the scope of the Quality/Environmental Management System, the details of and justification for any exclusion, the documented procedures or reference to them, and a description of the processes of the QMS or EMS and their interactions.

Information about the organisation, such as name, location and means of communication, should be included in the quality/environmental manual. Additional information such as its line of business, a brief description of its background, history and size may also be included. The content of the manual is usually short and the information is without unnecessary details. It is quite common to include the organisation's policy in the management system.

Title and scope

The title and/or scope of the manual should define the organisation to which the manual applies. The manual should make reference to the specific Quality/Environmental Management System standard on which the QMA or the EMS respectively is based.

Table of contents

The table of contents of the quality manual should list the number and title of each section and its location.

Review, approval and revision

Evidence of the review, approval, revision status and date of the quality manual should be clearly indicated in the manual.

Quality policy and objectives

Where the organisation elects to include the quality policy in the quality manual, the QMS/EMS manual may include a statement of the quality policy and the objectives for quality. The actual quality/environmental goals to meet these objectives may be specified in another part of the QMS/EMS documentation as determined by the organisation.

The quality/environmental policy should include a commitment to comply with requirements and continually improve the effectiveness of the QMS or EMS.

Objectives are typically derived from the organisation's quality policy and are to be achieved. When the objectives are quantified they become goals and are measurable.

Organisation, responsibility and authority

The quality/environmental manual should provide a description of the structure of the organisation. Responsibility, authority and interrelation may be indicated by such means as organisation charts, flow charts and/or job descriptions. These may be included or referenced in the quality manual.

References

The quality/environmental manual should contain a list of documents referred to but not included in the manual.

QMS/EMS description

The manual should provide a description of the QMS or EMS and the implementation of it into the organisation. Descriptions of the process and their interactions should be included in the quality or environmental manual.

Documented procedures or references to them should be included in the quality manual.

The organisation should document its specific QMS or EMS following the sequence of the process flow or the structure of the selected standard or any sequencing appropriate to the organisation. Cross-referencing between selected standards and the quality manual may be useful.

The quality/environmental manual should reflect the methods used by the organisation to satisfy its policy and objectives.

Appendices

Appendices containing information supportive to the manual may be included.

Procedures

To ensure that procedures are maintained as current documents and to reinforce the concept of ownership, the people that are working with these documents and were involved in the design, should be made responsible for the maintenance of the system documentation.

The simplest way to prepare process definitions and procedures is during a series of workshops supervised by these people and attended by their colleagues who are also involved in the process or procedure. An alternative way to a procedure could be flow charts, method statements, drawings etc.

A process in the standard is described as a set of interrelated or interacting activities, which transform inputs in outputs.

In other words, processes are those chains of activities that take place across an organisation and deliver the organisation's products or services to either internal or external customer.

Processes are what need to be done, who needs to do it and what is the result.

Procedures will support the processes. Procedures and other documents like work instructions define how an activity is required to be done.

System process and procedures should reflect the existing working practices and identify the interfaces with the function's internal and/or external customers and suppliers.

The draft procedures are then circulated to interested parties. They are invited to submit comments within a given timeframe after which the procedure will be finalised.

It is vital that all the documentation of a QMS/EMS will be handled swiftly and endless circulation for comments will be prevented.

It is recommended to write the system procedures by following the sequence of the clauses or structure as close as possible. This facilitates document reviews and auditing activities.

Structure and format

The structure and format of the documented procedures should be defined by the organisation in the following way: text, flow charts, tables, a combination of them, or any other suitable and clear method in accordance with the needs of the organisation.

Documented procedures may make reference to work instructions that define how an activity is performed.

Documented procedures generally describe activities that cross-different functions while work instructions generally apply to tasks within one function only.

Contents

Also the contents and layout show normally a strict set-up that makes it easy for people involved to make new draft procedures themselves. Usually the following headings will be found.

Title

The title should be clearly identifying the subject of the procedure.

Purpose

The heading Purpose should define the purpose of the document.

Scope

The scope of the documented procedure, including the areas to be covered and the areas not to be covered, should be described.

Responsibility and authority

The responsibility and authority of people and/or organisational functions.

Description of activities

The level of detail may vary depending on the complexity of the activities, the methods used, and the levels of skills and training of the people that is necessary in order for them to accomplish the activities within the expected timeframe and the needed skills.

Irrespective of the level of detail, the following aspects should be considered as applicable:

- *Defining the needs of the organisation, its customers and its suppliers.*
- *Describing the processes in terms of text and/or flow charts related to the required activities.*
- *Establishing what is to be done, by whom or by which organisational function, why, when, where and how.*
- *Describing process controls and controls of the identified activities.*
- *defining the necessary resources for the accomplishment of the activities (in terms of personnel, training, equipment and materials)*
- *Defining the appropriate documentation related to the required activities.*
- *Defining the input and output of the process.*
- *Defining the measurements to be taken.*

Records

The records related to the activities in the documented procedure should be defined in this section of the documented procedure or in other related sections. The forms to be used for these records should be identified as applicable. The method required to complete, file and keep the records should be stated.

Appendices

Appendices containing information supportive to the documented procedure may be included, such as tables, graphs, flow charts and forms.

Review, approval and revision

Evidence of review and approval, status and date of revision of the documented procedure should be indicated.

Identification of changes

Where practicable, the nature of the change should be identified either in the document or the appropriate attachments.

Work instructions

Structure and format

Work instructions are also called sometimes operating procedures. Work instructions should be developed and maintained to describe the performance of all work that would be adversely affected by lack of such an instruction. There are many ways of preparing and presenting instructions.

Work instructions should contain the title and a unique identification.

The structure, format and level of detail used in the work instructions should be tailored to the needs of the organisation's personnel and depends on the complexity of the work, the methods used, training undertaken, and the skills and qualifications of such personnel. The structure of the work instructions may vary from that of the documented procedures. The work instructions may be included in the documented procedures or referenced in them.

Contents

Work instructions should describe critical activities. Details, which do not give more control of the activity, should be avoided. Training can reduce the need for detailed instructions, provided the persons concerned have the information necessary to do their jobs correctly.

Types of work instructions

Although there is no required structure or format for work instructions, they generally should convey the purpose and the scope of the work and the objectives, and make reference to the pertinent documented procedures.

Whichever format or combination is chosen, the work instructions should be in the order of sequence of the operation, accurately reflecting the requirements and the relevant activities. To reduce confusion and uncertainty, a consistent format or structure should be established and maintained.

Work instructions are usually the responsibility of the department who has the main responsibility for the activity or activities documented in the instruction.

Work instructions are structured according to operational requirements of the organisation, which is usually by department

Review, approval and revision

Where applicable, the records specified in the work instruction should be defined in this section or in other related sections. The minimum records required are identified in ISO 9001/ISO 14001. The method required to complete, file and keep the records should be stated. The forms to be used for these records should be identified as applicable.

Identification of changes

Where practicable, the nature of the change should be identified either in the document or in the appropriate attachments.

Forms

Forms are developed and maintained to record data demonstrating compliance to the requirements of the QMS or EMS.

Forms should contain a title, identification number, revision level and date of revision. Forms should be referenced in, or attached to, the quality/environmental manual, documented procedures and/or work instructions.

Quality plans

A quality plan is a part of the Quality Management System documentation.

The quality plan needs to refer only to the documented Quality Management System, showing how it is to be applied to the specific situation in question, and identify and document how the organisation will achieve those requirements that are unique to the particular product, process, project or contract.

The scope of the quality plan should be defined. The quality plan may include unique procedures, work instructions and/or records.

Specifications

Specifications are documents stating requirements. Specifications are not further detailed in this guide because they are unique to each organisation and product or service.

External documents

The organisation should address external documents and their control in its documented QMS/EMS. External documents can include customer drawings, specifications, statutory and regulatory requirements, standards, codes and maintenance manuals.

Records

Quality and Environmental Management System records state results achieved or provide evidence indicating that the activities indicated in the documented procedure and work instructions are performed. The records should indicate the compliance with the requirements of the Quality and Environmental Management System and the specified requirements for the product. The responsibilities for preparation of records should be addressed in the Quality and Environmental Management System documentation.

Use the examples on the following pages.
Then go back to 2.1 and implement the QMS.



euromining

QMS
Uncontrolled copy if printed.
Page X of XX

Revision:
Revision date:
Approved by:

Quality Management System Manual

0. Table of contents

Subject	Description	Page
1	Scope and policy	2
1.1	General	2
1.2	Application	2
2	Normative reference	3
3	Terms and definitions	3
4	Quality management system	3
4.1	General requirements	3
4.2	Documentation requirements	3
4.2.1	General	3
4.2.2	Quality manual	4
4.2.3	Control of documents	4
4.2.4	Control of records	4
5	Management responsibility	4
5.1	Management commitment	4
5.2	Customer focus	4
5.3	Quality policy	5
5.4	Planning	5
5.4.1	Quality objectives	5
5.4.2	Quality management system planning	5
5.5	Responsibility, authority and communication	5
5.5.1	Responsibility and authority	5
5.5.2	Management representative	5
5.5.3	Internal communication	5
5.6	Management review	6
5.6.1	General	6
5.6.2	Review input	6
5.6.3	Review output	6
6	Resources management	6
6.1	Provision of resources	6
6.2	Human resources	6
6.2.1	General	6
6.2.2	Competence, awareness and training	6
6.3	Infrastructure	7
6.4	Work environment	7
7	Product realisation	7
7.1	Planning of product realisation	7
7.2	Customer-related processes	7
7.2.1	Determination of requirements related to the product	7
7.2.2	Review of requirements related to the product	8
7.2.3	Customer communication	8
7.3	Design and development	8
7.3.1	Design and development planning	8

7.3.2	Design and development inputs	8
7.3.3	Design and development outputs	8
7.3.4	Design and development review	9
7.3.5	Design and development verification	9
7.3.6	Design and development validation	9
7.3.7	Control of design and development changes	9
7.4	Purchasing	9
7.4.1	Purchasing process	9
7.4.2	Purchasing information	9
7.4.3	Verification of purchased product	10
7.5	Production and service provision	10
7.5.1	Control of production and service provision	10
7.5.2	Validation of processes for production and service provision	10
7.5.3	Identification and traceability	10
7.5.4	Customer property	10
7.5.5	Preservation of product	10
7.6	Control of monitoring and measuring devices	11
8	Measurement, analysis and improvement	11
8.1	General	11
8.2	Monitoring and measurement	11
8.2.1	Customer satisfaction	11
8.2.2	Internal audit	12
8.2.3	Monitoring and measurement processes	12
8.2.4	Monitoring and measurement of product	12
8.3	Control of non-conforming product	12
8.4	Analysis of data	12
8.5	Improvement	13
8.5.1	Continual improvement	13
8.5.2	Corrective action	13
8.5.3	Preventive action	13

1. Scope

1.1 General and policy

The quality manual outlines the policies, procedures and requirements of the quality management system. The system is structured to comply with the conditions set forth in the international standard ISO 9001:2000

Quality policy

The management team of the organisation and all its employees are committed to the quality of our products and the stated quality objectives.

We are striving to achieve the industry's leading position in quality of our products.

We will maintain a quality management system to meet requirements of the ISO 9001:2000 standard.

We will continually improve the level of customer satisfaction

Our employees will recognise the organisation as the best organisation to work for.

We will develop and promote a culture of continual improvement of our products and the quality management system.

We will maintain a profitable operation to establish our competitive position in the market and reward our shareholders.

We will meet the needs and expectations of all our shareholders.

The management team will periodically review the performance of the quality management system and quality objectives to ensure their effectiveness and continuing suitability.

1.2 Application

The organisation has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

Identify permissible exclusions. If none, document that there are no exclusions.

Document the justification for any exclusion that is made.

2.0 Quality management system references

The following documents were used as reference during the preparation of the quality management system:

- ISO 9000-2000, Quality Management Systems - Vocabulary.
- ISO 9001-2000, Quality Management Systems – Requirements
- ISO 9004-2000, Quality Management Systems – Guidelines for Performance Improvements

3.0 Quality management system definitions

This section is for definitions unique to the organisation.

- Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- Customer supplied product - Any type of service or material supplied to be utilised in the manufacture, modification or repair of customer-owned property.
- Product – The end item result of meeting all contract terms and conditions. (e.g.: manufactured goods, merchandise, services etc.)
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable

4. Quality management system

4.1 General requirements

The organisation has established, documented and implemented a quality management system (QMS) in accordance with the requirements of ISO 9001:2000. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS the organisation has:

- Identified the processes needed for the QMS and their application throughout the organisation and documented them on the process flow diagram at the end of this section of the quality manual
- Determined the sequence and interaction of these processes, and illustrated them on the process flow diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented them in quality plans, work instructions and the measuring, monitoring and analysis table

- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure and analyse these processes.
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

4.2 Documentation requirements

4.2.1 General

The QMS documentation includes:

- a documented quality policy
- this quality manual
- documented procedures
- documents identified as needed for the effective planning, operation and control of our processes, and
- quality records

4.2.2 Quality manual

This quality manual has been prepared to describe the organisation's QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The process flow diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.

4.2.3 Control of documents

All of the QMS documents are controlled according to the document control procedure.

This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified and their distribution controlled, and
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose

4.2.4 Control of quality records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the control of quality records procedure. This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

Related documents

Document control procedure

Quality records procedure

5.1 Management commitment

Top management has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct management reviews.
- Ensure the availability of resources.

5.2 Customer focus

The organisation strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations.

Top management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures.

Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in the organisation.

5.3 Quality policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organisation.

Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organisation. The quality policy is documented and part of the manual.

5.4 Planning

5.4.1 Quality objectives

Quality objectives are established to support our organisation's efforts in achieving our quality policy and reviewed annually for suitability. Objectives have been established for the following: Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

An organisational chart has been established to show the interrelation of personnel in the organisation. Job descriptions define the responsibilities and authorities of each of the positions on the organisational chart. Job descriptions and the organisational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organisation to help employees understand responsibilities and authorities.

See the organisational chart below. (To be filled in)

5.5.2 Management representative

The quality manager has been appointed by top management as management representative.

As management representative, he/she have the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organisation.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

5.5.3 Internal communication

Processes are established for communication within the organisation. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication.

5.6 Management review

5.6.1 General

Top management reviews the QMS periodically at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

5.6.2 Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system

- Recommendations for improvement

5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review

Related documents

Customer related processes
Management review procedure
Planning of product realisation processes

6.1 Provision of resources

The organisation has implemented a quality management system that complies with the ISO 9000 2000 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

6.2 Human resources

6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, awareness and training

Qualifications are reviewed upon hiring, when an employee changes positions or the requirements for a position change. Human resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the training procedure.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

To meet quality objectives and product requirements the organisation has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in quality plans. Existing

infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventive maintenance plans
- Sanitation plans
- Building maintenance plans
-

6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Related Documents

Competence, awareness and training
Infrastructure

7.1 Planning of product realisation

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Planning of Product Realisation procedure. During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, validation, monitoring, inspection and test requirements, and
- Criteria for product acceptance

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organisation determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by the organisation

Customer requirements are determined according to the customer related processes procedure.

7.2.2 Review of requirements related to the product

The organisation has a process in place for the review of requirements related to the product. The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined

Contract or order requirements differing from those previously expressed are resolved

- The organisation has the ability to meet the defined requirements
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, the organisation communicates changes to relevant personnel and amends relevant documents

7.2.3 Customer communication

The organisation has implemented an effective procedure for communicating with customers in relation to:

- Product Information
- Enquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

7.3 Design and development

7.3.1 Design and development planning

The design and development procedure outlines the process for controlling the design and development process. The R&D Department plans design and development according to this procedure. The design plan includes:

- Design and development stages
- Required design reviews
- Verification and validation methods appropriate to each design and development stage
- Responsibilities and authorities for design and development
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses

7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure. All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development

7.3.3 Design and development outputs

Outputs of design and development are documented according to the design and development procedure. They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements
- Provide appropriate information for purchasing, production and for service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings, which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfil requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed

7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Design and Development procedure.

7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

7.3.7 Control of design and development changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including where appropriate:

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of purchased product

The purchasing procedure describes the process used to verify that purchased product meets specified purchase requirements. If the organisation or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

The organisation plans and carries out production and service provision under controlled conditions according to documented procedure. Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring devices
- The implementation of monitoring and measurement
- The implementation of release, delivery and post-delivery activities

7.5.2 Validation of processes for production and service provision

The organisation validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

The organisation has documented the process for validation including:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation

7.5.3 Identification and traceability

The organisation identifies the product throughout product realisation according to the identification and traceability procedure. Product is identified with respect to monitoring and measurement requirements.

The organisation controls and records the unique identification of the product where ever traceability is a specified requirement

7.5.4 Customer property

The organisation exercises care with customer property while it is under the organisation's control or being used. A procedure outlines the identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

7.5.5 Preservation of product

The organisation preserves the conformity of product during internal processing and delivery to the intended destination per procedure. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of monitoring and measuring devices

The organisation has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards
- Adjusted or re-adjusted as necessary;
- Identified to enable the calibration status to be determined;
- Safeguarded from adjustments that would invalidate the measurement result;
- Protected from damage and deterioration during handling, maintenance and storage.

In addition, quality control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Related Documents

Planning of product realisation processes
Customer related processes
Design and development
Purchasing
Control of production and service provision
Identification and traceability
Customer property

Preservation of product

Control of monitoring and measuring devices

The organisation has plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity of the product,
- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organisation monitors information relating to customer perception as to whether the organisation has fulfilled customer requirements. The method for obtaining and using this information is identified in the customer related processes and the management responsibility procedures.

8.2.2 Internal audit

The organisation conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organisation
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the internal audit procedure.

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Related documents

Internal auditing procedure

8.2.3 Monitoring and measurement of processes

The organisation applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the monitoring,

measuring and analysis of product realisation processes and management responsibility procedures.

8.2.4 Monitoring and measurement of product

The organisation monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realisation process identified in monitoring, measuring and analysis of product realisation processes.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorising release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.3 Control of non-conforming product

The organisation ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with non-conforming product are defined in the control of non-conforming product procedure.

Related documents

Non-conforming products procedure

8.4 Analysis of data

The organisation determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analysing this data is defined in the management responsibility procedure. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

8.5 Improvement

8.5.1 Continual improvement

The organisation continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organisation takes action to eliminate the cause of non-conformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the non-conformities encountered.

A documented procedure defines requirements for

- Reviewing non-conformities (including customer complaints),
- Determining the causes of non-conformities,
- Evaluating the need for action to ensure that non-conformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing corrective action taken.

Related documents

Corrective action procedure

8.5.3 Preventive action

The organisation determines action to eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure defines requirements for:

- Determining potential non-conformities and their causes
- Evaluating the need for action to prevent occurrence of non-conformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing preventive action taken

Related documents

Preventive action procedure

Related Documents

Management responsibility

Customer related processes

Monitoring, measuring and analysis of customer satisfaction

Internal auditing procedure

Monitoring and measuring of product and realisation processes

Non-conforming products procedure

Corrective action procedure

Preventive action procedure

Document control procedure

Quality records procedure

Management review procedure

QMS Procedure nr.
Uncontrolled copy if printed.
Page X of X

Revision:
Revision date:
Approved by:

Corrective Action Procedure

Scope: This procedure covers the method for taking action to eliminate the cause of non-conformities in order to prevent recurrence. This procedure is used to analyse and remove root cause of actual non-conformities within the Quality Management System and to process customer complaints.

Responsibility: The Management Representative is responsible for overseeing the implementation of the corrective action process and of the Corrective Action Request (CAR) form. Top management is responsible for the final approval of the actions taken.

Procedure:

Any employee

1. Any employee receiving customer complaint or judging that a system non-conformance needs attention of management to remove root cause will document on a CAR form, the type of non-conformance and describe the situation requiring root cause analysis.
2. Forward the form to the Management Representative.

Management Representative

1. The Management Representative will determine the proper employee to process the root cause analysis and assign this person. Records the assignment on the CAR form.
2. Enter the CAR form into the CAR log under the date of the start of the assignment followed by a three-digit unique sequence number.
3. Copy the CAR form, store it and return the original to the assignee.

Assignee

1. Determine and document the root cause of the situation.
2. Determine and document the actions needed remove the root cause and prevent the reoccurrence of future non-conformities.
3. Implement the actions.

4. Record the findings and results taken and the apparent effectiveness of these actions. If this is a customer complaint, contact the customer, direct or indirect, and verify the solution with the customer. Document this contact and resolution on the CAR form.
5. Return the CAR form to the Management representative.

Management Representative

1. Review the CAR form for completion of all necessary steps. Follow-up with the assignee if needed.
2. Submit the CAR form into the next Management Review Meeting for final approval. If the CAR form is approved, document the closure in the CAR log and replace the temporary copy of the CAR form with the signed original.

If top management refuses to approve the CAR-form, assist the assignee and repeat the appropriate steps.

References:

ISO 9001:2000

CAR form

CAR log

Management Review Meeting

QMS Procedure nr.
Uncontrolled copy if printed.
Page X of X

Revision:
Revision date:
Approved by:

Document Control Procedure

Scope: This procedure covers the method to control the needed documents of the Quality Management System, including the quality policy, quality objectives, quality manual and its procedures.

Responsibility: The Management Representative is responsible to ensure that the quality manual, procedures and other applicable documents are kept up to date and available to the employees.

Procedure:

Approval

The highest executive position at the site (Managing Director) approves the quality manual, procedures, the quality policy and the objectives prior to issue. Each will be signature-approved or included in a signature-approved document.

The management representative will approve any other documents created for the quality management system.

Re-approval

When any of the above documents are revised, they will be retrieved and re-approved by the same authority as the original approval. For the quality manual and the procedures, the new revision dates will be listed in the quality manual table of contents

The management representative will review the quality manual and the procedures at least once a year. Proof of this review will be signing of the Annual Review page in front of the quality manual.

Revisions status

For the quality manual and procedures, any changes will appear in red text with the old text lined out. The current revision will be listed in the header of the document and will match the current revision date listed in the quality manual table of contents. Changes to the quality policy or quality objectives will not use this method; only a re-approval signature and the current date will be sufficient. Any changes to existing records will be lined out with a new entry.

Available at point of use.

The Management Representative will make sure that all employees have access to the latest version of the quality manual, procedures and other needed documents at the point of use or as near as practical to the point of use.

Legibility and identification

The Management Representative will oversee these documents and ensure that they remain legible. The header of the quality manual and procedures will state the title of the document. The quality manual, quality objectives and any other documents will each be identified by their title.

Documents of external origin

Documents of external origin are those documents created outside of the Quality Management System but referenced in internal documents, such as the quality manual and procedures, as needed for operating the quality management system. The Management Representative will write in the applicable documents of external origin and the applicable revision date of each. The Management Representative will keep this list current.

Prevention of unintended use

The Management Representative will retain obsolete revisions of the Quality Manual and its procedure, the quality policy and the objectives.

There is no requirement to keep any obsolete revisions of any of the documents mentioned in this procedure. However, if any obsolete revision is kept for any reason, it must be clearly marked as OBSOLETE.

References:

ISO 9001:2000

Quality Manual

Quality Procedures

Quality Policy

QMS Procedure nr.
Uncontrolled copy if printed.
Page X of X

Revision:
Revision date:
Approved by:

Internal Auditing Procedure

Scope: This procedure covers the methods for performing internal audits.

Responsibility: The Management Representative is responsible for overseeing the implementation of the internal audits, including planning, conduction the audits, reporting the results to top management and maintaining the records.

Procedure:

1. The quality system is internally audited at least once a year. Various areas of the quality system may be audited more frequently based on status and importance.
2. The quality system will be audited sufficiently to determine if it meets the planned arrangements of the system and the ISO 9001:2000 standard, including the effective implementation and the maintenance of the system.
3. Each internal audit will be planned (by using the Internal Audit Plan), taking into consideration, the results of the previous audits of this area. The audit criteria and scope shall be documented in each plan.
4. Standard internal auditing methods as those stated in ISO 11011 will be used when conducting the internal audits. Trained internal auditors, independent of the area audited, or outsourced to a consultant with at least three years of experience in quality system implementation and auditing, will conduct the internal audits.
5. The internal audit results will be documented in a report to top management and the management of the area audited. The auditor will enter each internal audit non-conformances on the Internal Non-conformance Form and process according to the requirements listed on the form.
6. The manager responsible for the area being audited will determine the corrective action, and ensure that actions are taken without undue delay to eliminate the detected non-conformities and their causes. The follow-up by the original auditor will verify the effectiveness of the actions taken to correct the non-conformance. This verification will be recorded on the internal audit non-conformance form. The form will be returned to the Management Representative for overall audit closure and record retention.

References:

ISO 9001:2000

ISO 11011

Internal Audit Plan

Internal Non-conformance Form

QMS Procedure nr.
Uncontrolled copy if printed.
Page X of X

Revision:
Revision date:
Approved by:

Management Review Procedure

Scope: This procedure covers the methods for performing periodic management reviews.

Responsibility: The Management Representative is responsible for overseeing the implementation of the management reviews, including planning, preparation and reporting the results and decisions taken and maintaining the records.

Purpose:

1. The quality management system in use will be regularly reviewed by top management at least once a year, to ensure:
2. That it continues to be effective and suitable – fulfilling the changing and future needs of the organisation and its customers.
3. That the Quality Management System is updated and adequate as necessary.
4. That the results of internal audits are reviewed, to ensure that the defined objectives of Quality Management System are realised and the system is properly being implemented and used.

Procedure:

The Managing Director will, or the delegated Management Representative will:

1. Call management reviews at regular intervals – not greater than 12 months, or more frequently at its discretion.
2. Decide who should attend, including the Managing Director and the Management Representative.
3. Allocate follow-up actions and time scales to specific personnel based upon the processed or being processed non-conformity reports (NCR), preventive action reports (PAR) and corrective action reports. (CAR)

The Managing Director or the Management Representative will:

1. Provide a summary of the Internal Audit reports that have been completed since the last management review meeting.
2. Archives the minutes of the meeting as quality records
3. Provide a summary of the corrective action reports (CAR) and the preventive action reports (PAR) and the customer complaints raised since the previous management review meeting – paying particular attention to those, which remain unsolved.
4. Provide a summary of supplier and subcontractor performance reports since the last management review meeting.

References:

ISO 9001:2000

PAR form

NCR form

CAR form

Internal Audit Report

Minutes of Management Review Meeting

Supplier/Subcontractor Performance Report SPR

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QMS Procedure nr.
Uncontrolled copy if printed.
Page X of X

Revision:
Revision date:
Approved by:

Non-Conforming Products Procedure

Scope: This procedure covers the method for controlling non-conforming products or services. It includes the decision on how to process the non-conformance and a record of the decision.

Responsibility: The Managing Director will make decisions on how to disposition non-conformances. The Managing Director will may delegate this authority when appropriate. The Management Representative will keep track of the Non-Conformance Reports (NCR) in a Non-Conformance Report system.

Procedure:

When any employee identifies a non-conforming situation, it will be brought to the attention of the Managing Director. The Managing Director will initiate the attached NCR as follows:

1. Clearly document the situation or occurrence, including the date, on the NCR form.
2. As appropriate, the Managing Director will select one of the following choices to disposition the non-conformance.
 - a. Take action to eliminate the non-conformance.
 - b. Authorise its use, release acceptance under concession by his/her authority, and where applicable, by the customer.
 - c. Take action to preclude its original intended use or application.

The decision must be recorded on the NCR form that is forwarded to the Management Representative to be entered into the NCR system.

Any non-conforming product or service resulting in corrective action shall be subject to re-verification to demonstrate conformity to the requirements.

When non-conforming product or service is detected after delivery or use has started, the organisation shall take action appropriate to the effects of the non-conformity. This may include completing the NCR form or completing a Corrective Action Request (CAR) as a customer complaint.

All NCR will be evaluated in the following Management Review Meeting.

References:

ISO 9001:2000

NCR form

CAR form

Management Review Meeting

QMS Procedure nr.
Uncontrolled copy if printed.
Page X of X

Revision:
Revision date:
Approved by:

Preventive Action Procedure

Scope: This procedure covers the method for taking action to prevent potential non-conformities. This procedure is used to analyse and remove the potential cause of non-conformities within the quality system.

Responsibility: The Management Representative is responsible for overseeing the implementation of the preventive action process and the preventive action report (PAR) form. Top management is responsible for the final approval of the actions taken.

Procedure:

Any employee

3. Any employee identifying a potential non-conformity within the quality system will document the situation on a PAR form as the situation requiring analysis.
4. Forward the form to the Management Representative.

Management Representative

4. The Management Representative will determine the proper employee to evaluate the need for action to prevent occurrence of the non-conformity, and will record the assignment on the PAR form.
5. Enter the PAR form into the PAR log under the date of the start of the assignment followed by a three-digit unique sequence number.
6. Copy the PAR form, store it and return the original to the assignee.

Assignee

6. Evaluate and document the need for action to prevent occurrence of the non-conformity.
7. Determine and document the actions needed to prevent the occurrence of the non-conformance.
8. Implement the actions.
9. Record the findings and results taken and the apparent effectiveness of these actions on the PAR form.
10. Return the PAR form to the Management representative.

Management Representative

3. Review the PAR form for completion of all necessary steps. Follow-up with the assignee if needed.
4. Submit the PAR form into the next Management Review Meeting for final approval. If the PAR form is approved, document the closure in the CAR log and replace the temporary copy of the PAR form with the signed original.
If top management refuses to approve the PAR-form, assist the assignee and repeat the appropriate steps.

References:

ISO 9001:2000

PAR form

PAR log

Management Review Meeting

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QMS Procedure nr.
Uncontrolled copy if printed.
Page X of X

Revision:
Revision date:
Approved by:

Quality Records Procedure

Scope: This procedure covers the method for controlling the records required by the Quality Management System. These records are maintained to provide evidence of conformity to requirements and the effective operation of the Quality Management System.

Responsibility: The Management Representative is responsible to ensure that the quality manual and its procedures are kept up to date and available to the employees.

Procedure:

Legible

Quality records will be maintained so that they can be readable throughout the retention period.

Identification

Quality records will be identified according to the title at the top document or on a cover page when applicable.

Retrievable

Using the Quality Records Matrix (QRM) the person desiring legitimate access to a record, can retrieve the record using the retention time, storage location, storage format, identification of indexing method, and disposition requirement, if any.

If no disposition requirement is listed, the record may be disposed at the discretion of the person responsible for the original filing.

References:

ISO 9001:2000

QRM