DNV·GL

ISO 9001:2008 GUIDANCE DOCUMENT QUALITY MANAGEMENT SYSTEM

This guide is relevant to ISO 9001:2008. In 2015 there was a revision to the standard.
For the information on ISO 9001:2015 please visit www.dnvgl.com.

FACTS

4 QUALITY MANAGEMENT SYSTEMS

4.1 General requirements

The general requirements outline what constitutes the basis of a quality management system, a broad view of what needs to be done. The aim of which is to facilitate development of a system that will achieve the business quality objectives. Items a) through to f) provide a systematic approach to building such a system. One made up of processes, which should be managed in accordance with the requirements of the standard.

It should be recognised that the system should include all processes needed to achieve the objectives. That means processes needed for; managing the organisation, managing resources, making and/or delivering product or service and measurement.

Any process that is outsourced also needs to be identified within the Quality Management System (QMS) and controlled by the organisation. A classic example of this is maintenance of process equipment and organisational infrastructure. Organisations cannot simply pass activities on to subcontractors or suppliers and not exert some controls over them.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There are no specific documentary requirements in this clause. It merely reflects the fact that the system will be documented. The extent of that documentation will be determined by the organisation according to need.

FACTS

4.2 Documentation requirements

4.2.1 General

Formal quality management systems are sometimes perceived as nothing but large collections of documents. This is a great misconception. Documentation is there as an aid to manage risk.

This general requirement outlines what constitutes the quality system documentation required by the standard. Whilst some documentation is mandatory, a great deal of flexibility is given to the organisation in deciding what documents it requires to ensure adequate planning, operation and control of its processes.

This will greatly depend upon; the size of the organisation and type of activities; the complexity of processes and their interactions; the competencies of personnel.

Another point to note is that a record is a document. However, as we will see in the next few clauses, records are controlled in a different way to other documents.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Quality policy and objectives must be documented and there must be a quality manual, which by definition is a document. Other documentation such as procedures and records are indicated as being necessary but are not determined or specified in this clause.

4.2.2 Quality manual

A quality manual must be produced. Its purpose is to provide an over- view of the system and allow users to find information.

There is no defined format for a quality manual. The choice of format and content is purely a matter for the organisation. However, it must contain; the scope of the QMS (e.g. the manufacture of wooden doors), including justification for any exclusions (e.g. where there is no design process); documented procedures, or reference to them; a description of process interaction (e.g. an in-sequence flow chart of the quality system processes).

It should be noted that outsourcing an activity is not justification for exclusion. The organisation is still responsible for the results and must place controls on such an activity.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Quality manual and possibly records of it revision and distribution.

4.2.3 Control of documents

System documentation needs to be controlled. That includes documents received as well as documents produced internally.

The aim is to ensure that the right document is in the right place at the right time. Only through controlling documentation can it be ensured that the right information is being communicated to the right people.

Control should ensure that those reviewing documents are competent and that revision status is identified and traceable. Distribution should ensure that those that need the documents have access to them, and that obsolete documents are dealt with correctly.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

A documented procedure is required and there would also be records of review and approval, distribution and recall. There may also be a master list of all documentation and a revision history.

4.2.4 Control of records

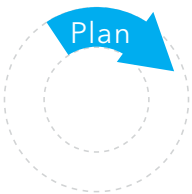
Records are those documents that provide evidence of conformance. They can be regarding product, process and/or system. Forms, once complete, often become records (e.g. checklists, inspection reports, etc.).

It is up to the organisation to determine exactly which records are required and how long they should be retained for. However, requirements for some records are stipulated in the standard and may further be stipulated in; procedures, contracts, legislation, etc.

The organisation will also need to determine who will keep the records and for how long, how they should be kept and where, and what should be done with them once they are no longer required.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There may be a master list of records. A documented procedure is required to control records but that does not mean there will be one control procedure covering all records.



FACTS

5 MANAGEMENT RESPONSIBILITY

5.1 Management commitment

No system will achieve its true potential without the commitment of Top Management. Evidence is required to demonstrate such commitment, particularly with regard to the development, implementation and improvement of the system.

Such commitment can be demonstrated through creating a quality culture, providing clear direction, ensuring the availability of adequate resources and reviewing progress.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Whilst there are no specific document requirements, evidence can be provided through training records, policies and objectives, budgets and plans, and meeting minutes.

5.2 Customer focus

Without knowing what our customers want, how can we expect to deliver? The aim of this requirement is to fully determine market/customer needs and expectations. This information then acts as one input to determining strategy, which in turn provides direction and facilitates development of a system capable of satisfying the targeted market or customer.

This is an on-going process, which can be achieved by many different means.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Whilst not specified, documents/records might include market surveys, meeting minutes, questionnaires, and others.

5.3 Quality policy

The policy is a very important document because it acts as the driver for the organisation. It provides the direction and formally establishes goals and commitment.

It is the responsibility of Top Management to ensure that policy is set and appropriate. It should not be some bland statement that could apply to any organisation. It must provide clear direction to allow meaningful objectives to be set in-line with it.

Once set, the policy needs to be communicated to all employees that are involved in achieving it. They need to understand what part they have to play in its deployment.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Policy must be documented and some form of document control would need to be applied.

5.4 Planning

5.4.1 Quality objectives

As part of the planning process top management needs to set quality objectives. These objectives are what make the policy a reality. As such they should be consistent with policy and be capable of being measured.
When setting objectives the current and future needs of the organisation should be considered as well as the market served.

There are many different types of objectives; market position and/or growth, process effectiveness and/or efficiency, awareness levels, maintenance of present position, etc. Whilst improvement is necessary, objectives do not have to be for improvement only.

The objectives need to be deployed throughout relevant parts of the organisation and must be meaningful to those who are assigned responsibility for achieving them and those whose activities contribute to achievement.

They must also be measurable.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Objectives must be documented and there will need to be evidence regarding monitoring of achievement. There will also be baseline data on which the objectives are bases.

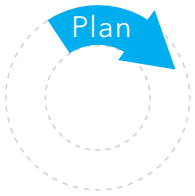
5.4.2 Quality management system planning

Having established the quality objectives, the organisation must plan how they are going to achieve them. This would involve determination of structure, roles and responsibilities, processes and interaction, resources, information, communication, etc.

Planning should be consistent with the systems approach. It is realised that business is dynamic and as such there will be change. Change management processes must ensure that the integrity of the system is not damaged during change and that the system continues to function properly.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

The output of system planning would need to be described in the quality manual. The manual should reflect the system.



FACTS

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

For a system to function effectively and efficiently those involved need to be fully aware of their role. Top Management must ensure that responsibility and authority are clearly defined and that everybody involved understands what they can and should do.

Defining roles is a function of planning, ensuring awareness can then be achieved through communication and training.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Whilst not required, it is common for organisations to use job descriptions or procedures. Again, these would be the subject of document control. It may also be felt necessary to have awareness training records.

5.5.2 Management representative

Within any system there is a need to channel information. This could be said to be the primary role of the management representative (MR). It is not the responsibility of the MR to implement the system, but to ensure implementation and provide feedback on performance.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Some organisations choose to officially appoint the MR. There may also be compiled data for reporting purposes.

5.5.3 Internal communication

Communication is essential to the effective functioning of any system, Top Management need to ensure that mechanisms are in place to facilitate this.

It should be recognised that communication is two-way and will not only need to cover what is required, but also what resulted. In other words, what was planned and what was achieved?

Mechanisms for communication could include; meetings, notice boards, in-house publications, awareness raising seminars, toolbox talks, intranet, email, etc.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Some organisations see communication as being important enough to warrant a documented communication procedure. Whilst this is not required there is at least likely to be some reference in procedures.

FACTS

5.6 Management review

5.6.1 General

The main aim of management review is to ensure the continuing suit- ability, adequacy and effectiveness of the QMS. Only through conducting the review at sufficient intervals, providing adequate information and ensuring the right people are involved can this aim be achieved.

There is information that is considered essential for this purpose and as such the standard details the minimum inputs to the review process.

Top Management should also use the review as an opportunity to identify improvements that can be made and/or any changes required, including the resources needed to realise this.

5.6.2 Review inputs

Describes the minimum inputs

5.6.3 Review outputs

Describes typical outputs.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Records of the review are required to be maintained. This will usually be in the form of meeting minutes but may also be in the form of a report, notated with required actions after its review.

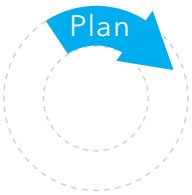
IMPACT

Exercise 11: Management Responsibility

Imagine that you are the "skeptical" Chief Executive of an organisation. You're not particularly interested in what ISO9001 has to offer your business. You simply need a certificate to enable you to carry on trading with one of your major customers.

In your teams discuss what is the minimum that you feel you can "get away with doing" to comply with the requirements of Clause 5 of the standard.

Produce a list of your findings.



FACTS

6 RESOURCE MANAGEMENT

6.1 Provision of resources

An effective and efficient QMS cannot be maintained or improved without adequate resources. As a function of planning, such resources should be determined, and then provided. This includes contract or project specific resources.

The standard puts resources into the following three categories; human, infrastructure, work environment.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Whilst not required, annual budgets, organisation

charts, project/production plans are just some of the types of documents which could be utilised to demonstrate adequate planning of resources.

6.2 HUMAN RESOURCES

6.2.1 General

The main intention behind this general requirement is that the people working within the quality system are competent to fulfil the duties of the assigned function.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

See below.

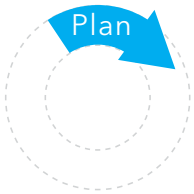
6.2.2 Competence, training and awareness

In order to determine competence, competence criteria need to be established for each function affecting quality. This can then be used to assess existing competence and determine future needs. Where criteria are not met some action is required to fill the gap. Training or reassignment may be necessary. Regardless of the action taken, effectiveness will need to be evaluated to ensure competence exists in relation to criteria/needs.

Personnel also need to be made aware of the relevance of their activities and how they contribute to organisational quality objectives. Induction programmes and staff reviews are often used for this purpose.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Records are required to be able to demonstrate competence. Recruitment and induction programmes, training plans, skills tests and staff appraisals often provide evidence of competence and the assessment thereof. Competency requirements are often included in recruitment notices and job descriptions.



FACTS

6.3 Infrastructure

Again, for a system or process to operate effectively and efficiently there must be adequate buildings, equipment, transport, etc. Determining what is needed and what maintenance programme should be developed to ensure its continuing capability is part of planning. Obviously the plan should then be implemented.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There is no specified documentation required but annual budgets, organisation charts, project/production plans and the like might indicate what was planned. Maintenance programmes and records could also be used to ensure optimisation.

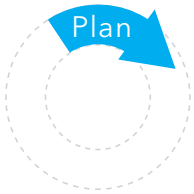
6.4 Work environment

The work environment of an organisation has many human and physical factors that can influence quality, effectiveness and efficiency. Such factors that have influence need to be identified and managed. They can include; creative work methods, protective equipment, ergonomics, heat, noise, light, hygiene, humidity, vibration, etc.

An example of a work environment issue would be humidity in a paint shop. Compliance with acceptable humidity levels during painting would need to be monitored.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Again there are no specific documentary requirements but work environment criteria are often found in procedures, contracts, specifications, codes of practice and the like. Organisations would need to provide evidence of compliance through records.



FACTS

7 PRODUCT REALISATION

7.1 Planning of product realisation

Product realisation processes are those processes that are required in order to realise the product. In other words they are a sequential series of processes

which determine requirements and convert those requirements into a delivered product that meets requirements.
The above are often referred to as core business processes. However, they are reliant on other processes, often referred to as support processes (e.g. training, documentation, maintenance etc.).

Product realisation processes need to be planned and developed. In some organisations planning happens infrequently because the product is always the same. In others it happens with every contract or order.

Where a certain activity is not undertaken and not necessary to fulfill requirements, (e.g. where there is no design) the respective requirements of the standard can be excluded.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There are no specific documentary requirements in this clause. The output of planning should be in the form most suitable to the organisation. That could be; drawings, specifications, procedures, method statements, quality plans or any combination of these and others. Planning should also include what records will be needed as evidence of compliance.

FACTS

7.2 Customer related processes

7.2.1 Determination of requirements related to the product

There must be a process to ensure that needs and expectations of customers (requirements) are determined. This should include determination of intended product use and any statutory regulations that would apply to the product in its intended market.

Only once all requirements are identified can they be reviewed.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

See below.

7.2.2 Review of requirements related to the product.

Once determined, requirements need to be reviewed by the organisation prior to commitment to supply, to ensure that they are understood, that any anomalies are resolved and that the organisation has the ability to meet the requirements. All too often offers are made and orders accepted without fully understanding need and capability.

Review would need to be undertaken during enquiry handling and again, albeit to a lesser degree, during acceptance of a contract/order and when handling amendments.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Examples of input documentation would be; enquiries, specifications and clarifications, whilst examples of output documents could be offers, tenders and contractor proposals. Also, subsequent amendments and related communication records.

7.2.3 Customer communication

The need for communication will differ according to many factors; customer, internal need, contract, risk, project complexity etc. Obviously it will take place as part of the determination and review processes detailed above, but it will also need to take place during production and possibly after delivery.

Communication needs to be planned to ensure that all necessary information is available when needed, from both external and internal sources. This will include feedback from the customer, which is further discussed under the specific heading of customer satisfaction.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

No communication documents are specified but organisations normally determine what documents need to be maintained. Typically they consist of contracts, specifications, emails, letters, transmittals and attachments, meeting minutes, complaints etc.

IMPACT

Exercise 12: Customer-related Processes – Clause 7.2

In your teams review the following scenario and determine which, if any, of the requirements of Clause 7.2 have not been complied with.

In the production department there is a batch of components (identification number 6633) which has recently been manufactured.
The items are labelled "HOLD PENDING CONCESSION" and are the first batch to be made for a recently received order.

The supervisor explains that these items have been manufactured in accordance with the relevant process control procedures and conform to the well-known and established capability of the production department but do not con- form to the customer's specification.

The sales department is currently discussing with the customer how to resolve this situation. Record your findings below.

FACTS

7.3 Design and development

7.3.1 Design and development planning

There must be a systematic approach to controlling design activities and product development. This will involve planning, which should include; stages of design, review, verification and validation activities; defined responsibilities; and management of the interfaces between various groups to ensure adequate communication.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Although not a specified requirement, a common document produced is a design plan, which outlines how the design will be managed through the whole design process.

7.3.2 Design and development inputs

The information required in order to proceed further with the design process must be determined, recorded and reviewed for adequacy.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

This may include; customer specification; statutory requirements; information from previous designs etc., and associated review records.

7.3.3 Design and development outputs

How the design is developed is a matter for the each organisation to decide. However, the design output needs to be verified against the design input requirements. Therefore output needs to be in a format that will enable verification. Output also needs to; facilitate purchasing, production and servicing processes; show or give direction to acceptance criteria; specify characteristics essential to safe use.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Typical out puts include drawings, specifications, instructions, schedules, user manuals, etc.

7.3.4 Design and development review

Review of the design should be undertaken as planned, to ensure that design progress is satisfactory and to trigger solutions to any problems being encountered.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Results of review and necessary actions need to be recorded. Typically these would include meeting minutes, altered drawings, sketches, approval documents etc.

7.3.5 Design and development verification

Verification is basically a process whereby the design is checked to ensure that what has been designed meets the input requirements. For example, checking design calculations to ensure that an air conditioning unit has the desired capacity.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

The results and any actions required as a result must

be recorded. Typically these would include alternative calculations, approvals, stamps, comparison reports, etc.

7.3.6 Design and development validation

Validation needs to be performed, as planned, to ensure that the product can do what it was designed for. For example, testing a prototype air conditioning unit to ensure it can hold the desired temperature under the defined operating condition used as the basis for the design.

Validation should, where possible, be completed prior to delivery.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Results and any actions need to be recorded. Typically these would include test results, prototype user feedback, etc.

7.3.7 Control of design and development changes

Changes to design requirements can come at any time and as a result of many factors. They can also significantly impact on what has already been designed. Any resulting changes in design must be reviewed and verified and validated where necessary.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Design changes need to be identified, documented and recorded. Typically these could include internal memos, customer or legislative correspondence.

IMPACT

Exercise 13: Design & Development – Clause 7.3 – A Quiz!

In your teams you are required to review the requirements of Clause 7.3 and produce 5 questions to test the knowledge and understanding of the other participants.

A short quiz will be held between the teams. You can record your questions here.

FACTS

7.4 Purchasing

7.4.1 Purchasing process

In essence, the main aim of this requirement is to ensure that purchased products or services will meet requirements. As a first step it is necessary to have confidence in the entity supplying the product or service. Therefore it is required that an evaluation process is in place.

This evaluation process should be flexible, as not all suppliers have the same impact on the purchasers' final product. The criteria for selection, evaluation and re-evaluation of suppliers must be determined. Controls could then be put in place based on the results of the evaluation and the relative impacts they could have (risk management).

Suppliers need to be re-evaluated periodically. This can be done through performance records.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

The results of supplier evaluation and re-evaluation need to be maintained. Typically these would be in the form of references, trial orders, product specifications, audit results, performance data etc. Whilst not required, an approved supplier list is often compiled for easy reference.

7.4.2 Purchasing information

The second step to ensuring that purchased product meets requirements is to provide all the necessary information. The supplier should not have to second guess what is needed. Clarity is essential, not just in terms of product specification but also in terms of operator qualification, quality control, quality assurance, documentation, delivery, etc. The purchase requirements should also be checked for adequacy before they are communicated to the supplier.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Typical documentation would include supplier quotation analysis, purchase orders, contracts, and associated review records.

7.4.3 Verification of purchased product

The third step involved is verification of the product or service. This may be done by various means at the pre-shipment stage or upon receipt. For example, receiving inspection or test, or through verifying a certificate of product conformance.

Verification activities that are to take place at the suppliers' premises need to be detailed in the purchase information.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

No documentation specified but could include; purchase information, sampling plans, inspection/test reports, conformance certificates, acceptance criteria etc.

IMPACT

Exercise 14: Purchasing - Clause 7.4 – True/False

In your teams you are required to review the requirements of Clause 7.4 and then identify which of the following statements are true or false:

	Statement	T/F
1	Everything that an organisation buys is rquired to be purchased from a supplier who has been evaluated	
2	Organisations are required to produce a list of Approved Suppliers	
3	Purchase orders must be signed as evidence of checking prior to issue to a supplier.	
4	All items purchased by an organisation must be subjected to the same level of checking to confirm they meet requirements	
5	Data about the performance of suppliers needs to be collected and analysed	

FACTS

7.5 Production and service provision

7.5.1 Control of product and service provision

In essence, this requirement is aiming to ensure that production activities and operations are planned and then carried out as per the plan in order to ensure control. This includes those operations at the customer premises, such as installation.

Control is necessary to achieve the desired result, not just in terms of product but also in terms of effectiveness and efficiency.

There are many different ways to achieve control. The standard lists them in a very generic format.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There are no specific documentary requirements in this clause. The output of planning should be in the form most suitable to the organisation. That could be; drawings, specifications, work instructions, quality plans, operating and process criteria.

7.5.2 Validation of processes for production and service provision

This requirement applies to products that cannot be truly verified until they are in use. An example of this is a match. The only really effective way to ensure that a match will work properly is to strike it. Obviously this cannot be done for every match. Therefore we must have confidence in the ability of the process to consistently produce the same match.

We also re-validate the process from time to time because conditions, people and materials can change.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Process validation records are required and may consist of records of operator qualification,
materials used, equipment used, method used, work environment conditions, and others.

7.5.3 Identification and traceability

In almost all organisations there is a need to identify product or service and determine its status or level of readiness at any given point in time. There may also be the need to trace product or service. The main aim is to be able to prevent incorrect use of suitable products or prevent or limit the use of unsuitable products.

In some industries traceability is a requirement throughout processing and beyond to assist in the event of recall. In such cases unique identification of the product needs to be controlled and recorded.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There are many different ways to identify and trace products/service. Batch numbers, production dates, inspection reports, colour coded labels, designated storage locations, packaging, service reports, job numbers, parts numbers, configuration management etc.

7.5.4 Customer property

Some organizations utilise products or intellectual property (e.g. patents) provided by customers. Where this is so it is necessary to ensure that what has been given is suitable for the intended application and thereafter is used properly and protected so that it is not lost or damaged.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Whilst not specified there may need to be records of receipt, inspection, use, loss, damage or return.

7.5.5 Preservation of product

It almost goes without saying that all product needs to be preserved, from raw materials during receipt, storage and processing to finished product up to the point of delivery. The aim is continued suitability for use.

When planning preservation one should consider the needs of customers and regulators and identification, handling, packaging, storage and protection.

The type of product will naturally dictate the infrastructure and controls necessary. Frozen food for example will require cold storage and be governed by regulation, whereas other products may just need protection from direct sunlight.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

No documents are stipulated in the standard but documentation may include; storage procedures and criteria, records of receipt and issue legal compliance, nonconforming product, expiry dates, damaged or lost goods, returns etc.

FACTS

7.6 Control of monitoring and measuring equipment

The main aim of this requirement is to ensure that the necessary measuring equipment is available and in a known state of accuracy so as to provide assurance and evidence that product meets requirements. This includes software.

The organisation must determine what monitoring and measuring has to be undertaken and thereafter provide evidence that it was under- taken using correct and reliable equipment.
Regular calibration and maintenance is one way to provide confidence that results can be relied upon. Others might include procedures for handling, use and storage.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Records of calibration are required but in addition to this there may also be calibration methods, calibration lists, records of validity checks, error acceptance criteria, maintenance records, etc.

FACTS

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

When developing a system it is necessary to plan what needs to be measured and how the results will be used to identify where improvement are required or desired. Such checks and analysis are an essential part of the P-D-C-A cycle.

The focus should be on what is critical; product, process, system, business goals, customer. This will avoid unnecessary measurement and analysis.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There will inevitably be some documented procedures describing methodology and criteria. There will also be templates designed to capture relevant data, which will become records. There will also be results of analysis.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Customer feedback is one very good indicator of system and business performance and there are many ways to capture such feedback. Questionnaires are not the only solution and are often ineffective. Some other methods are; interviews, meetings, market surveys.

The aim is to monitor information that will help determine customer perception of product and/or service and facilitate analysis so as to focus attention where it is needed to improve or enhance satisfaction levels where necessary.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There may be completed feedback forms or questionnaires. Alternatively there may be results of analysis of existing data (e.g. complaints, maintenance calls, meeting minutes).

8.2.2 Internal audit

The aim of the audit process is to determine the degree of conformance, implementation and effectiveness of the QMS and provide information to facilitate change and improvement.

An audit programme needs to be established to ensure that all processes are audited at the required frequency, the focus being on those most critical to the business objectives and success.

To ensure that audits are consistent and thorough, a clear objective and scope should be defined for each audit. This will also assist with auditor selection to ensure objectivity and impartiality.

To get the best results, auditors should have a working knowledge of what is to be audited. However, they must not audit their own work.
Management must act upon audit results. This is often limited to corrective action relating to non-conformance, but other findings can also be used to trigger prevention and improvement.
Follow up activities should be performed to ensure that necessary action has been taken and is effective.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

A documented procedure is required. There will also need to be an audit programme and records of audit results – not just nonconformity notices. In addition there will be follow up records and may be other documents such as checklists and auditor training records.

8.2.3 Monitoring and measurement of processes

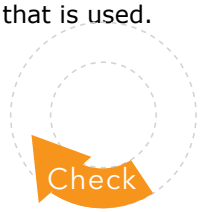
Whilst the audit process measures the system, it will still be necessary to monitor and in some cases measure individual processes. When a process is planned it should have a clear objective or purpose. The main purpose of monitoring or measuring the process is to determine if it is achieving this objective or purpose.

There are many different ways to monitor or measure a process; cycle time, waste, rejects, costs, variability, etc. Obviously those most suitable should be chosen.

Where the process is not effective it is an indication of a problem that needs to be corrected and as such appropriate action should be taken.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

Whilst no documentation is specified as required, there will inevitably be some process output information and it is this data that is used.



FACTS

8.3 Control of nonconforming product

This requirement is intended to ensure that nonconforming product is prevented from further processing, use or delivery.

Once identified, and regardless of when identified (e.g. during processing or after delivery) any nonconforming product should trigger a process whereby an authorised and competent person should decide what course of action to take. Options include scrap, concession, alternative use, product rework or recall and others relative to the product or service.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

A documented procedure is required to control the process of handling non-conforming product, as are records of such products that show what action was taken.

FACTS

8.4 Analysis of data

Collection and analysis of relevant data is necessary to measure the suitability and effectiveness of the QMS and to identify opportunities for improvement. As such business goals and objectives should considered when deciding what to analyse.

Methods of analysis varyggreatly in terms of applicability and complexity. Simple Bar Charts are sufficient for some activities whereas Statistical Process Controls are necessary for others. The methods selected should only be as complex as is needed to reach the desired conclusions relative to what is being analysed.

As a minimum, analysis should be performed in relation to customers, product conformance, processes and supplier performance. However, there are other valuable sources of information that can be utilised e.g. employees.

The main aim is identification of prevention and improvement opportunities.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There are no specified documentary requirements but there will be raw data and resulting analysis in the form of charts, graphs, percentages, distribution curves, standard deviation etc.

FACTS

8.5 Improvement

8.5.1 Continual improvement

One of the aims of any organisation should be to improve, and this should be a permanent objective. Such a commitment will have already been indicated in the policy. The aim of this requirement is to drive improvement of the systems effectiveness.

There are many ways to identify and drive improvement. All measurement results can be analysed to determine where improvement is required or desired. Policy and objectives can then be set and deployed through prevention and improvement programmes.

Improvement does not have to take place in all areas of the business at the same time. Focus should be relevant to risks and benefits.
Improvement can be incremental (small changes) or breakthrough (new technology). In reality both methods will be used at some point in time.

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DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

There may be specific improvement objectives.

8.5.2 Corrective action

The main aim of the corrective action process is to eliminate the causes of actual problems so as to avoid recurrence of those problems. It is a reactive process, in that it is triggered after an undesired event e.g. discovery of nonconforming product.

In essence the process focuses on root cause analysis. If we adopt the standard approach to problem solving, that being CAUSE and EFFECT, it is the cause that needs to be eliminated. The effect is handled when controlling the actual non-conformance.

Action taken should be appropriate to the impact of the problem (risk). As part of the corrective action process, the effectiveness of action taken must be checked to ensure its effectiveness.
It is worth noting that corrective action by its self will not bring about improvement in the QMS. It merely brings the control level back to where it should have been before the non-conformance occurred.

8.5.3 Preventive action

A similar set of requirements, but now of course dealing with potential problems rather than actual ones.

DOCUMENTATION AND RECORDS REQUIRED WITHIN THIS CLAUSE

A documented procedure is required and results of action taken must be recorded. Other documentation would be results of investigation in to the magnitude of the problem and the cause(s).

About DNV GL - Business Assurance

Driven by our purpose of safeguarding life, property and the environment, DNV GL enables organizations to advance the safety and sustainability of their business. DNV GL is a leading provider of classification, certification, verification and training services. With our origins stretching back to 1864, our reach today is global. Operating in more than 100 countries, our 16,000 professionals are dedicated to helping our customers make the world safer, smarter and greener. As a world-leading certification body, DNV GL helps businesses assure the performance of their organizations, products, people, facilities and supply chains through certification, verification, assessment, and training services. We also deliver deep insight and pragmatic support to major companies enabling them to build effective sustainability strategies. Partnering with our customers, we build sustainable business performance and create stakeholder trust.

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