DNV·GL

ISO 9001:2015
QUALITY MANAGEMENT
SYSTEMS – REQUIREMENTS
Guidance Document

Introduction

This DNV GL guidance document aims to gives a basic overview of the changes to ISO 9001, resulting from the review and revision of the 2008 standard. It is not intended to give an exhaustive and in-depth explanation of all requirements in the new standard.

ISO standards are reviewed and revised on a regular cycle, typically every 5-10 years, and 2015 sees ISO 9001:2008 reaching the end of that review process. A draft international standard (DIS) was published, and after extensive review the final draft international standard (FDIS) was published in July. The ISO 9001:2015 standard was published in September 2015.

The International Standards Organization (ISO) has developed a common Higher Level Structure (HLS) for management system standards, issued under an ISO Directive;

http://www.iso.org/sites/directives/directives.html

That directive has a series of annexes, of which we are interested in "Annex SL – Proposals for management systems standards". This annex states that all management system standards will use a consistent structure, common text and terminology, and this is enacted through "Appendix 2 – High level structure, identical core text, common terms and core definitions".

Some revised and new standards have already implemented this requirement – for example ISO 27001:2013 Information Security Management Systems (revised) and ISO 55001:2014 Asset Management Standard (new).

ISO 9001 has been revised in accordance with the new HLS and, as is the case with other HLS-based standards, it also contains additional discipline-specific content.

A whole range of country-level committees feed into the overall ISO committees which meet to decide on the revisions. The committee for ISO 9001 is TC 176. If you are a member of IRCA, or a trade federation, you can get access to the latest version of the draft Standard(s) and even comment on the content.

After the new standards are published, there will be a transition period for fully complying with them. This period will be 3 years, but it is strongly recommended that you start thinking now about how it will impact you, and review what changes might be needed.

How we can help

We are here to support you during the transition, through;

- direct contact, e.g. with your lead auditor as part of scheduled audits
- open webinars and transition training
- classroom transition training courses – tailored to your needs
- gap analysis, either as a separate activity or combined with scheduled audit activity
- combination of training and gap analysis
- "Questions on the ISO 9001:2015 and ISO 14001:2015 revisions" – LinkedIn discussion group

Layout of ISO 9001:2015

1	**Scope**
2	**Normative References**
3	**Terms and definitions**
4	**Context of the organization**
4.1	Understanding the organization and its context
4.2	Understanding the needs and expectations of interested parties
4.3	Determining the scope of the quality management system
4.4	Quality management system and its processes
5	**Leadership**
5.1	Leadership and commitment
5.2	Policy
5.3	Organizational roles, responsibilities and authorities
6	**Planning**
6.1	Actions to address risks and opportunities
6.2	Quality objectives and planning to achieve them
6.3	Planning of changes
7	**Support**
7.1	Resources
7.2	Competence
7.3	Awareness
7.4	Communication
7.5	Documented information
8	**Operation**
8.1	Operational planning and control
8.2	Requirements for products and services
8.3	Design and development of products and services
8.4	Control of externally provided processes, products and services
8.5	Production and service provision
8.6	Release of products and services
8.7	Control of nonconforming outputs.
9	**Performance evaluation**
9.1	Monitoring, measurement, analysis and evaluation
9.2	Internal audit
9.3	Management review
10	**Improvement**
10.1	General
10.2	Nonconformity and corrective action
10.3	Continual improvement

1. Scope

This section explains the scope of the standard – i.e. what it is for and what it encompasses. It introduces the requirements of a quality management system which supports the delivery of a product or service, through the application of effective and continually improving systems, assuring conformity to customer and applicable legal requirements, whilst enhancing customer satisfaction.

The section on "Application" in ISO 9001:2008 has been dropped, along with reference to "exclusions" (see ISO 9001:2015 clause 4.3).

2. Normative references

ISO 9000:2015, Quality management systems – Fundamentals and vocabulary is normatively referenced within ISO 9001:2015.

3. Terms and definitions

This clause simply references back to ISO 9000:2015 (see clause 2).

4. Context of the organization

This clause sets out the requirements for an organization to take a high level overview of the business, considering the key internal and external factors which impact it, and how it should respond in the form of a defined management system.

4.1 Understanding the organization and its context

This clause requires the organization to consider a wide range of potential factors which can impact on the management system, in terms of its structure, scope, implementation and operation.

Impacting factors can be of internal or external nature, and are wide-ranging;

- External factors can arise from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

- Internal factors may be related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

Clause 4.2 requires the organization to determine the need and expectations of "interested parties", both internal and external. Previous versions of the draft standard also contained the term "stakeholder", which many organizations will be more familiar with – the terms are synonymous and there is no need to consider them to be any different. Interested parties could include;

- Employees
- Contractors
- Clients/Customers
- Suppliers
- Regulators
- Shareholders
- Neighbours
- Non-Governmental Organizations (NGOs)
- Parent organizations

What is clear is that whilst the consideration of context and interested parties needs to be relevant to the scope and the standard, the assessment needs to be appropriate and proportionate.

What is also clear is that the output from clauses 4.1 and 4.2 is a key input to the assessment and determination of risks and opportunities required in clause 6.

In terms of demonstrating compliance, the ISO 9001 makes it clear that;

"The organization shall monitor and review the information about these external and internal issues" (clause 4.1).

"The organization shall monitor and review the information about these interested parties and their relevant requirements" (clause 4.2).

The above implies that there will need to be some form of retained documented information of this to evidence how internal and external factors and the views of interested parties have been considered. There are various methods and approaches which can be used to capture these inputs.

As with any significant revision to standards, hopefully there will be the development of a range of methods and examples for this. Some current examples include;

Internal and External Issues

- Key economic and market development which can impact on the organization; your organization is probably acutely aware of what is happening in its markets but it may be undertaken in a very ad-hoc way
- Technological innovations and developments; this is also an area critical to your business success and is also probably being monitored and discussed at numerous levels
- Regulatory developments; a whole range of external regulations are being monitored by your organization. If you miss them then it could seriously damage your business, or if you capture early intelligence on them you could realize better opportunities
- Political and other instabilities; if for example you rely on raw materials from one particular country which experiences major instability your whole business could be jeopardized; or if there are major ethical concerns regarding a source of materials or goods
- Organizational culture and attitudes; an effective and motivated workforce will give you positive impacts, and many organizations canvas feedback from employees

Internal and External Parties

- Stakeholder engagement exercises; already widely used to consult with interested parties and map

out concerns and issues. More often utilized by larger organizations engaging with corporate social responsibility initiatives
- Consultation meetings with neighbourhoods and NGOs on environment, planning and development issues; these are often used by major industrial plants with significant HSE risks
- Meetings and other interactions with regulators; this can encompass for example quality-critical issues on product specifications and conformity as well as developing compliance requirements and standards
- Employee meetings, consultations and feedback activities; this should be happening already, but maybe this will prompt more efforts to improve an area which has been at risk of "lip service" to ISO 9001:2008
- Supplier reviews and relationship management; many organizations are trying to get much more mutual benefit from the supplier-client relationships which are critical to mutual success
- Client/customer reviews and relationship management; of course this is a fundamental pillar of all standards and a key to success
- It may be that when you reflect on how you capture key issues, and how many interested parties you engage with already you may be pleasantly surprised. It may be that you only engage with a limited number of internal and external parties, but now is the time to start thinking about whether that is enough, and whether you are missing some good opportunities.

There will be many ways in which to capture this – and hopefully some improved and new approaches might emerge as this part of the standard is considered. Approaches could include;

- Summary information from the range of existing approaches used as listed above (e.g. a brief report)
- Information summarized as part of inputs to risk and opportunity registers
- Recorded in a simple spreadsheet
- Logged and maintained in a database
- Captured and recorded through key meetings

These clauses are asking organizations to think clearly and logically about what can internally and externally affect their management systems, and be in a position to show that this information is being monitored and reviewed. It also requires organizations to elevate the discussions to the highest levels, since capturing the above range of information is hard to achieve without senior management involvement.

4.3 Determining the scope of the quality management system

This clause should be familiar to most organizations, since ISO 9001:2008 clause 4.2.2 required the definition of the scope of the management system. For ISO 9001:2015 the scoping requirements have become more stringent and require the organization to consider the inputs from 4.1 and 4.2, along with the products and services being delivered.

For the defined scope of the quality management system, the organisation should apply all requirements of the standard if they are applicable. When any requirement is not applicable there needs to be a clear justification. The defined scope has to be made available and maintained as documented information. The standard states, 'Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction'.

These clearer requirements on scoping will drive clarity in the thinking of organizations in scoping the management system. Certification bodies will, as before, look at how organizations has defined its scope, ensuring that this is both appropriate and is reflected accurately by the management system and also in the scope of any certificate issued.

4.4 Quality management system and its processes

This clause basically states that the organization needs to establish, implement, maintain and continually improve a management system in order to deliver the required products, services and performance required under the scope. This should also be familiar to organizations which implement management systems in order to deliver compliance and improvement.

Where this clause is more focused is in requiring organizations to understand more about the range of processes relevant to the scope of the management system. The term process is defined as; "a set of interrelated or interacting activities which transforms inputs into outputs".

For those who are committed to a management system which is at the core of their business, this will probably already be an integral part of that system, although you might need to review how effectively you connect those processes and understand the influence and impact of those processes on each other and on the business.

This should also elevate the system in terms of its importance and value to the business, because it should drive more meaningful analysis of the key business processes and critical aspects of those processes. In practical terms it will require an organization to more fully analyse its processes and ensure that there is good understanding of how they interact with each other- and not operate as isolated procedures without overlap.

Clause 4 introduces some significant innovations to the management system world, and could represent a challenge to some organizations who have not viewed the management system as pivotal to the business, focussed as it is on raising management systems to a higher level and to be more central to the way an organization functions.

5. Leadership

This clause includes a good proportion of content which will be familiar from ISO 9001:2008 but also introduces some significant changes on overall leadership and commitment and the expectations for top management to engage more fully with the critical aspects of the quality management system.

5.1 Leadership and commitment

This clause encompasses a range of key activities which top management need in order to "demonstrate leadership and commitment with respect to the management system". Therein lies one of the innovations delivered by the common HLS – top management must show leadership of the management system rather than just demonstrate commitment to it. The standard is driving the oversight of the management system to the highest level of management and making it a key component of the organization and its core business processes and activities.

It doesn't mean that senior management have to be able to regurgitate the policy or recite the objectives and targets – what it means is that an internal or external interested party should feel entitled to have a discussion with leadership about core and critical aspects of the business, because these are at the heart of the management system.

A further aim of this requirement is to fully determine market/customer needs and expectations. This information then acts as an input into determining strategy, which in turn provides direction and facilitates development of a management system capable of satisfying   the targeted market or customer. This is an on-going process, which can be achieved by many different means. Whilst not specified in the standard, documented information could include market surveys, customer meeting minutes, questionnaires and other areas of research.

Customer focus has remained very similar in context to ISO 9001:2008, but has been extended to include determination of risk and opportunities that affect conformity of products and services.

5.2 Policy

The Quality Policy is an important document because it acts as the driver for the organization. It provides the direction and formally establishes goals and commitment. Top management should ensure the policy is appropriate and compatible with strategic direction. The policy needs to be communicated to all employees and they need to understand the part they have in its deployment.

ISO 9001:2015 adds requirements for the policy to be documented and, as appropriate, be available to interested parties.

5.3 Organizational roles, responsibilities and authorities

For a system to function effectively, those involved need to be fully aware of what their role is. Top management must ensure that key responsibilities and authorities are clearly defined and that everybody involved understands their role. Defining roles is a function of planning, ensuring awareness can then be achieved through communication and training. It is common for organizations to use job descriptions or procedures to define responsibilities and authorities.

In ISO 9001:2015, top management are more directly identified as being responsible for ensuring that these aspects of the system are properly assigned, communicated and understood.

The specific role of a Management Representative has been removed – the standard still contains all of the key activities and responsibilities of that previously identified role, but these now lie more directly within the core structure of the organization - including top management.

Clause 5 contains much familiar content, but with greater emphasis on leadership and commitment and the expectation that top management will be more actively engaged with the management system.

6. Planning

This clause is an excellent addition to ISO 9001:2015, introducing the concept of risk (and opportunity) via the HLS. DNV GL has been in the "risk" business for a very long time. As well as working with our customers to help manage risk, we have been delivering Risk Based Certification since 2004. This innovative approach is based on an audit being built around relevant areas of risk to the organization, auditing in depth to assess whether the organization is managing that risk effectively.

6.1 Actions to address risks and opportunities

In basic terms, this clause requires the organization to;

- Understand the range of risks and opportunities relevant to the scope of the organization and determine actions, objectives and plans to address them
- In understanding those risk and opportunities, use the inputs that the organization has identified in understanding its context as required in clause 4.1, and the views and inputs from interested parties in clause 4.2

The strength of this clause lies in both introducing the principles of risk and opportunity to management systems standards via the HLS, and by connecting it very clearly to the processes defined under clause 4 (the clause for determining the context of the organization and also considering the views and inputs from interested parties).

A well-established approach already implemented by many organizations is the use of risk registers, which if properly managed and implemented can effectively manage risks and opportunities across a wide range of areas and issues. There will also be other approaches which result from the various relevant clauses of 9001 (e.g. the results from clause 4.1 and 4.2) along with management of change, with an overall analysis and review resulting in objectives, targets and plans. The depth and complexity of approach will depend significantly on the size and complexity of the organization, as well as other factors which could include the level of external regulation, existing requirements for public reporting, shareholder interests, public profile, numbers and types of customers, range and types of suppliers. Hence there will be a range of approaches which will be appropriate for the wide spectrum of organizations.

It is worth reviewing the introductory clause 0.3.3 and Annex A.4 of the standard, which discusses the overall concept of "risk-based thinking", which covers the need for an organization to consider all aspects of risk, and the fact that the revisions to 9001 bring the concept of risk to the fore as a generic and fundamental term.

6.2 Quality objectives and planning to achieve them

As part of the planning process, top management needs to set quality objectives which will help to turn the Quality Policy into reality. Objectives should be consistent with the Quality Policy and be capable of being measured. This clause requires the organization to establish quality objectives and plans, ensuring that these are clear, measurable, monitored, communicated, updated and resourced.

There are many different types of objectives that could be considered; market position and/or growth, process effectiveness and/or efficiency, improved awareness levels, maintenance of present position, reduction in quality costs, improvements in product conformity/reduction in defect rates, improved customer satisfaction etc. The objectives need to be deployed throughout relevant parts of the organization and must be meaningful to those who are assigned responsibility for achieving them and those whose activities contribute to their achievement.

Documented information needs to kept in relation to objectives and there will need to be evidence regarding monitoring of achievement.

6.3 Planning of changes

This clause sets requirements to ensure that needed changes to the management system is carried out in a planned manner. This include to consider potential consequences of change, availability of resources and defining roles and responsibilities. Changes to the management system can be needed in case of acquisition of companies, introduction of new products and services etc.

7. Support

An effective quality management system cannot be maintained or improved without adequate resources. As a function of planning, such resources should be determined and provided. This includes contract or project specific resources. This clause gathers together in one place all the areas relating to the "people, place and procedural" aspects of the management systems. The basic HLS clauses cover the following;

- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented Information

7.1 Resources

The main intention behind this general requirement is that the people working within the quality management system are competent to fulfil their duties, supported by equipment and infrastructure that is fit for purpose. There must be adequate provision of infrastructure such as buildings, equipment, IT systems, transport, etc. Determining what is needed and what maintenance programme should be developed to ensure its continuing capability is part of planning.

The work environment of an organization has many human and physical factors that can influence quality, effectiveness and efficiency. These factors need to be identified and managed and can include; protective equipment, ergonomics, heat, noise, light, hygiene, humidity, vibration, temperature etc. The relevant factors are obviously different for each product or service.An example of a work environment issue could be control of humidity in a paint shop. There are no specific documentary requirements required by ISO 9001:2015, but work environment criteria are often found in procedures, contracts, specifications and codes of practice. Evidence of compliance should be available via retained documented information.

The organization must determine what monitoring and measuring has to be undertaken and provide evidence that it was undertaken using correct and reliable equipment. Regular calibration and maintenance (and retained documented information) is one way to provide confidence that results are reliable.

Critical measuring equipment must be available and in a known state of accuracy to provide assurance and evidence that products meet their relevant requirements. This also includes software.

For ISO 9001:2015, these familiar requirements relating to the provision of resources for the management system and the effective delivery of the scope of services are refreshed to reflect the fact that these assets can now be broader and can cover not just equipment and hardware.

There is also a very interesting additional requirement termed "organizational knowledge", which relates to ensuring that the organization understands internal and external knowledge needs and can demonstrate how this is managed. This could also include knowledge management of resources, and ensuring that there is effective succession planning for personnel, and processes for capturing individual and group knowledge.

7.2 Competence

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 even be necessary. Retained documented information is required to be able to demonstrate competence. Recruitment and induction programmes, training plans, skills tests and staff appraisals often provide evidence of competence and their assessment. Competency requirements are often included in recruitment notices and job descriptions.

7.3 Awareness

Personnel need to be made aware of the relevance of their activities and how they contribute to achievement of the quality objectives and the effectiveness of the management system and resulting organizational performance. Induction programmes and staff reviews are often used for this purpose.

7.4 Communication

ISO 9001:2015 brings (through the HLS) a clear emphasis on the importance of both internal and external communications (i.e. greater emphasis on external communication than the 2008 standard).

The clause emphasizes the need to plan and implement a process for communications along the familiar 'who, what, when, how' principles.

Effective communication is essential for a management 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 was achieved. In other words, what was planned and what was achieved? Changes in the quality management system should be communicated appropriately to interested parties (albeit in practice this is mainly internal parties) and should identify appropriate levels of re-training. Mechanisms for communication could include; meetings, notice boards, in-house publications, awareness raising seminars, toolbox talks, intranet, email, etc.

7.5 Documented information

Most of the ISO 9001:2015 text is familiar, being similar to the requirements of ISO 9001:2008, but there is some logical broadening to encompass electronic and web-based environments. It is worth emphasising here that the standard no longer mandates the need for documented procedures – it is up to the organization to decide what is needed. However, it does specify on a number of occasions the need to maintain or retain documented information, in order to give structure, clarity and evidence of the system being maintained and effective. The term "documented information" now replaces the previously used terms "documented procedure" and "records".

Documented information can be in any format as long as it provide appropriate evidence to demonstrate compliance, and such documented information does not mean there has to be a procedure for everything – in fact, it can be in any format decided by the organization.

With ISO 9001:2015, there is more additional text and a number of sub-sub-clauses, but these are mainly driven by the need to ensure that content from the existing ISO 9001:2008 is carried over into the appropriate and suitable clause of ISO 9001:2015.

In most areas this clause does not require any significant changes, but there are some of the additional requirements which will require some new thinking, particularly around organizational knowledge. The changes introduced with the HLS in terms of not specifically requiring documented procedures is in reality not a significant issue – organizations still need to look at where documented information (e.g. processes, procedures, data, records) is critical for the management systems and its effective operation.

8. Operation

This clause basically represents the production and operational control parts of the standard – the 'engine house' of production. There are a significant number of clauses added to the basic HLS.

8.1 Operational planning and control

This clause makes very clear statements about the importance of linking to the critical elements of clause 4.4 where the critical processes and their interactions are determined, and to actions determined in ch. 6. There are also some additional requirements on control of changes, which are made more explicit now, and also on control over outsourced processes (previously covered under the purchasing clause of ISO 9001:2008).

8.2 Requirements for products and services

There must be a process to ensure that the needs and expectations of customers (and their requirements) are determined. This should include the determination of the intended product use and any statutory requirements that apply to the product in its intended market. Only once all requirements are identified can they be reviewed.

Once determined, requirements need to be reviewed by the organization prior to any commitment to supply to ensure that they are understood, that any anomalies are resolved and that the organization has the ability to meet the requirements. There are numerous incidents of offers being made and orders accepted without fully understanding whether the business can meet the contract and has the capability to deliver. Examples of input documentation could be; enquiries, contract specifications and clarifications, whilst examples of output documents could be offers, tenders or contractor's proposals.

Communication needs to be planned to ensure that all necessary information is available when needed, from both external and internal sources. This could also include feedback from the customer, which is further discussed under the heading of customer satisfaction (clause 9.1.2). Documented information pertaining to communication are not specified, but typically they can include contracts, specifications, drawings, e-mails, letters, transmittals, meeting minutes, complaints etc.

ISO 9001:2015 adds content on communications relating to customer property along with contingency actions.

8.3 Design and development of products and services

There must be a systematic approach to controlling design activities and product development. This will involve design planning, which should include stages of design, review, verification and validation activities. Although not required by ISO 9001:2015, a common document produced is a design plan, which outlines how the design will be managed throughout the design process.

Design and development inputs can include customer specifications, statutory requirements, information from previous designs, budgetary considerations etc. Each organization should decide how the design is developed but the output needs to be verified against the design input requirements. Therefore, the output needs to be in a format that will enable verification. Typical outputs include drawings, specifications, instructions, schedules, user manuals etc.

Review of the design should be undertaken at planned stages to ensure that the design is satisfactory and to trigger solutions to any problems encountered. Documented information pertaining to design reviews and necessary actions needs to be retained. Typically these could include meeting minutes, altered drawings, sketches, approval documents etc.

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. The results and any actions required as a result of the verification process must be retained as documented information. Typically these could include alternative calculations, approvals, comparison reports etc.

Validation needs to be performed to ensure that the product can meet the basis of its design. For example, testing a prototype air conditioning unit to ensure it can hold the desired temperature under the defined operating conditions before mass production commences. Validation should, where possible, be completed prior to delivery. Results of the validation process and any actions need to be retained as documented information. Typically these could include test results, prototype feedback, user testing etc. Changes to design requirements can come at any time and as a result of many factors. They can also significantly impact on the design in progress. Any resulting changes in design must be reviewed, verified and validated where

necessary. Design changes need to be identified and retained as documented information.

This clause follows much of the ISO 9001:2008 clause 7.3, but with clearer structure and requirements for design and development planning, consideration of needs of customers and from key documented information (clause 8.3.2); for design and development inputs, a wider set of inputs including resource considerations and potential consequences of failures (clause 8.3.3). Clear requirements for retention of documented (design) information are stated.

8.4 Control of externally provided processes, products and services

The main aim of this requirement is to ensure that the purchased processes, products or services you require (e.g. components for your product) will ensure that you can meet your customer's requirements.

As a first step it is necessary to have confidence in the entity supplying the process, product or service. Some form of initial evaluation process should be in place, but this should be flexible as not all suppliers have the same impact on the final product/service. The criteria for selection, evaluation and re-evaluation of suppliers must be determined and applied. Controls could then be put in place based on the results of the evaluation and the relative impacts they could have (risk management) must be determined and applied.

A second step to ensuring that purchased process, product or service meets requirements is to provide all necessary information to the supplier. They should not have to second-guess what is needed, and clarity is essential, not just in terms of product specification but also in terms of operator qualification, quality control, quality assurance, documentation, delivery times etc.

The purchase requirements should also be checked for adequacy before they are communicated to your supplier. Typical documented information could include supplier quotations, purchase orders, contracts and associated review records.

A third step is the verification of the process, product or service that you have procured. This could be done by various means at the pre-shipment stage or upon receipt. For example, receiving inspection or test records, or through verifying a certificate of product conformity. Some organizations undertake audits of their key suppliers or witness factory acceptance tests. Activities could also involve your customer conducting a joint verification with you at their premises.

As a fourth step, suppliers need to be re- evaluated periodically (or continually) against pre-determined criteria. The results of supplier evaluation and re-evaluation need to be maintained, and could be in the form of references, trial orders, product specifications, audit results, performance data, defect rates etc.

Although not a requirement of the standard, some organizations choose to compile an approved supplier list for ease of reference.

ISO 9001:2015 covers much broader ground than ISO 9001:2008 in terms of referring to externally provided processes, products or services rather than the existing clause on purchasing. It also makes clear the criteria for applying the requirements.

8.5 Production and service provision

This requirement is aiming to ensure that your production activities and operations are planned and then conducted in a manner ensuring control. This can also include operations at the customers' premises, such as installation.

There are many different ways to achieve control and methods can include controlled processes, procedures, drawings, specifications, work instructions, quality plans, operating and process criteria.

This requirement applies to products that cannot be truly verified until they are in use (e.g. a match – as the only effective way to test whether a match will work is to strike it!). A business must have confidence in the ability of its process to consistently deliver and meet customer expectations. Processes may also need re-validation from time to time because conditions, people and materials can change. Retained documented information relevant to process validation is required and may consist of records of operator qualifications, materials used, equipment used, methods used, the work environment etc.

In almost all organizations there is a need to formally 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 a product or service (e.g. for legal requirements). 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. There are many different ways to identify and trace products/ services such as; batch numbers, production dates, inspection reports, colour coded labels, designated storage locations, packaging bar codes, service reports, job numbers, project/ report numbers, part numbers, configuration information etc.

Some organizations use products or intellectual property (e.g. patents) provided by customers. If so, then it is necessary to ensure that what has been provided is suitable for the intended application and thereafter is used properly and protected against loss or damage. To support this, there could be records of receipt, inspection, use, loss, damage or return (again there are clear requirements stated for retention of documented information).

Product need to be preserved - from raw materials during receipt, storage and processing to finished product up to the point of delivery. The aim is to ensure continued suitability for use. In the service industry this could also include the preservation of data or reports on electronic media. When planning preservation of products, there should be consideration of the needs of customers, regulators as well as identification, handling, packaging, storage and protection requirements. 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 may include storage procedures and criteria, records of receipt and issue, records to demonstrate legal compliance, expiry dates, damaged or lost goods, returns etc.

ISO 9001:2015 brings much that is similar in content and intent to the existing requirements in ISO 9001:2008. The main change is with the two additional clauses – "8.5.5 Post-delivery activities" and "8.5.6 Control of changes" – now much more clearly defined and specified.

8.6   Release of products and services

The organization must monitor and measure the characteristics of the product to verify that product requirements have been met and evidence of conformity with the acceptance criteria must be maintained. Retained documented information must indicate the person(s) authorising the release of product for delivery to the customer.

8.7   Control of nonconforming outputs

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 is to be taken. Options can include scrapping, supplying under concession, alternative uses, product rework or recall.

ISO 9001:2015 has broadened the terminology and scope of the operations and production clause, whilst retaining much of the ISO 9001:2008 content. The approach adopted is also aligned with the common process-based aspects of the HLS, and covers more effectively the complete end-to-end production and service provision process.

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

Collection and analysis of relevant data is necessary to measure the suitability and effectiveness of the management system and to identify opportunities for improvement. Business goals and objectives should considered when deciding what to analyse and comment.

Methods of analysis vary greatly 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 needed. As a minimum, analysis should be performed in relation to customers, product conformance, processes and supplier performance.

Customer feedback is one very good indicator of management system and business performance. There are many ways to capture feedback and businesses should think wider than just using questionnaires or complaints. For example, other methods include interviews, customer meetings and market surveys. The aim is to monitor information that will help understand customer perception of the product/ service and to facilitate analysis to improve satisfaction.

This clause contains familiar content on customer satisfaction and analysis and evaluation, with requirements broadly similar to ISO 9001:2008, but with a more holistic approach and a stronger drive for evidence of analysis and evaluation of key performance data as the basis of fact-based decision making.

9.2 Internal audit

Internal audits have always been a key element of ISO 9001 in helping to assess the effectiveness of the quality management system. 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. To ensure that internal 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, but management must act on audit results. This is often limited to corrective action relating to any nonconformities that are found, but other findings can also be used to trigger prevention and improvement.

Follow up activities should be performed to ensure that the action taken as a result of an audit is effective.

This clause is largely the same as in ISO 9001:2008.

9.3 Management review

The main aim of management review is to ensure the continuing suitability, adequacy and effectiveness of the quality management system, and its alignment with the strategic direction of the organization. Only through conducting the review at sufficient intervals (remember, management review does not have to be just one meeting, held once per year), providing adequate information and ensuring the right people are involved can this aim be achieved.

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.

The input to management review should include information on;

(a) the status of actions from previous management reviews;
(b) changes in external and internal issues that are relevant to the quality management system
(c) information on the performance and effectiveness of the quality management system
(d) Adequacy of resources
(e) the effectiveness of actions taken to address risks and opportunities
(f) Opportunities for improvement

The output from the management review shall include decisions and actions related to opportunities for improvement, need for changes to the quality management system and resource needs.

Documented information pertaining to the management review is required to be retained. This will usually be in the form of meeting minutes, but could also be in the form of a report, notated with required actions after its review (as the management review process does not necessarily have to be a meeting).

This clause is largely the same as ISO 9001:2008, but with some broader topics and alignment with the new language of risks and opportunities, and the context of the organization.

10. Improvement

10.1 General

This clause provides an overview of what improvement means in the context of ISO 9001:2015 – an overall approach requiring review of processes, products and services and quality management system results, with some useful reminders that the mechanisms for such improvements can be achieved by a variety of means; correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and 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 uses the principles of root cause analysis. A basic approach to problem solving is "cause" and "effect", and it is the cause that needs to be eliminated. 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 it is effective.

It is worth noting that corrective action alone will not bring about improvement in the quality management system. It merely brings the control level back to where it should have been before the nonconformity occurred. Additionally, although not an explicit requirement of the standard, corrective actions should also take into consideration any specific training and communications needs.

For the clause on nonconformity and corrective action, much of the content is familiar and similar to ISO 9001:2008 but the term "preventive action" has now been deleted from the requirements section of the standard (but gets a mention elsewhere in the context of risk-based thinking), the new HLS being built on the fundamental principles of risk management, which embodies the need to identify risk and manage those risks, with the ultimate goal of risk elimination.

10.3 Continual improvement

One of the aims of any organization should be to improve and this is a key tenet of ISO 9001. 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. The content of this clause on continual improvement is similar to ISO 9001:2008 and effectively re-emphasises elements of performance and improvement documented elsewhere in the standard.

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