

Guidelines on implementing ISO 9001:2015

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The document is the outcome of a technical round table CONFORMA ISO 9001:2015, which was attended by:

Valerio PAOLETTI	RINA Services	COORDINATOR
Andrea ALLOISIO	RINA Services	
Michele AVERSA	CSI	
Giulio BATTISTELLA	CSQA	
Massimo CASSINARI	ICMQ	
Luisa COLOMBO	DNV- GL	
Fiorenzo COSTA	AICQ SICEV	
Lionella DAGO	CSQA	
Valentina DORONZO	CONFORMA	
Lucio GALDANGELO	ICIM	
Roberto GRAMPA	ICMQ	
Lodovico JUCKER	BUREAU VERITAS	
Francesca MALINVERNI	IMQ	
Paola PACE	DNV-GL	
Alessandra PEVERINI	CERTIQUALITY	
Barbara RENALDI	RINA Services	
Angelo SALDUCCO	AICQ SICEV	

Marco CIBIEN from UNI participated in the document's review.

CONTENTS

Introduction..... 7

1 Scope 10

2 Normative references..... 10

3 Terms and definitions..... 10

4 Context of the organisation 10

5 Leadership 13

6 Planning..... 16

7 Support..... 19

8 Operation 24

9 Performance evaluation 31

10 Improvement 33

ANNEX – 1 35

ISO 9001:2008 to ISO 9001 - Correlation Matrix 35

ANNEX – 2 38

Examples of implementation of requirement 4.1 38

ANNEX - 3 39

“RISCHIO” IN ISO 9001:2015 Errore. Il segnalibro non è definito.

ANNEX - 4 45

Non-exhaustive examples of possible risks referable to the context/interested parties..... 45

ANNEX - 5 47

Considerations on how to conduct audits for conformity to ISO 9001:2015..... 47

“Guidelines on implementing ISO 9001:2015”

Introduction

Ever since the publication of the DIS version of ISO 9001, a number of initiatives have been undertaken aimed at providing information on the differences between the new standard and the previous edition, on the meaning of the new requirements and on the improvements introduced to increase an organisation's capacity to achieve the objectives which it sets itself when it adopts a quality management system.

Following the release of the FDIS (Final Draft International Standard) version, CONFORMA has drawn up the first edition of these guidelines with a slightly different aim in mind, to offer practical suggestions to both certification body auditors on what to expect to find in an organisation to be reasonably sure that the requirements of the new ISO 9001:2015 are being met, as well as to organisations which adopt this standard to demonstrate compliance and effectiveness of their management system. Following publication of the final version of this standard on 23 September 2015, these guidelines have been revised to take into account the very few amendments made with respect to the FDIS version.

In many respects, the 2015 edition of the standard is the result of a repositioning of requirements in relation to the “High Level Structure” (*ISO/IEC Directives Part 1-2014 (5th edition) / Annex SL*), but also introduces new concepts and requirements which deserve a more detailed examination.

These guidelines are the result of the experience and competence which the certification bodies belonging to CONFORMA have acquired through management system assessments and which, combined with a thorough knowledge of the relative reference standards, enables the most appropriate interpretation to be given of the applicable requirements and, in particular, effective audits to be carried out which can give added value to organisations, thereby avoiding excessive formalism.

This document cannot, of course, enter into the specifics of each organisation as there are too many variables, such as the type of product/service, size, operational complexity, context in which the organisation operates and above all the objectives an organisation sets itself when it adopts a quality management system. Therefore, it offers considerations of a general nature, which can be adapted to individual organisations to which the ISO 9001:2015 standard will apply.

The guidelines can be used as a reference to assess the compliance and effectiveness of a quality management system against the ISO 9001:2015 standard, contributing to a uniform assessment by auditors, an aspect which all parties concerned are interested in, with particular regard to accreditation bodies.

These guidelines are to be used in conjunction with the standard, which contains the requirements to be met. For each requirement of the standard, whose heading and numbering are given in the first column, considerations have been made concerning the requirement in question and possible evidence to be obtained during the audit. This can be particularly useful for both organisations already certified according to ISO 9001: 2008, which intend to prepare for and undergo an audit for the verification of compliance with the new standard as well as for organisations which are in the process of setting up and implementing a management system.

With reference to the part related to possible evidence, conditional terms have been used (*could; should;*) to indicate that what is stated may not be the only way to meet the requirement.

The annexes contain: a comparative table between the ISO 9001:2008 and ISO 9001:2015 standards, examples of implementation of the requirements as per point 4.1, a translation into Italian of document ISO/TC 176/SC2 N1222 which provides clarification on the “risk based approach” which it is necessary to bear in mind when determining the processes, an example of possible risks referred to the context in which the organisation operates and some considerations on how to approach an audit for compliance with the new edition of the standard.

UNI, recognising the value of the guidelines, has supported it and was particularly involved in the aspect related to consistency of the terminology with the body of legislation concerning quality management and conformity assessment.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
1 Scope	
2 Normative references	
3 Terms and definitions	
4 Context of the organisation	
4.1 Understanding the organisation and its context	
This point is completely new compared to the previous ISO 9001:2008 edition. The organisation shall determine and analyse the internal and external issues (positive and negative) which are relevant to its strategic objectives and which influence its ability to obtain the results expected from its quality management system. The objective is to increase the organisation's strategic vision level when designing its quality management system, bearing in mind the context in which it operates. It is essential to identify the factors which can influence the organisation's ability to achieve the desired results in order to reason according to "Risk Based Thinking" (see 6.1) and consequently, to suitably define and develop the quality management system. For an overall view of the internal and external factors which influence the organisation, it may be appropriate to involve different sectors: marketing and sales, purchasing, administration and finance, human resources, technical management, production. Some examples, not exhaustive, are given in annex 2 on how the requirement may be applied.	The requirement does not specify how to give evidence of this analysis. Specific reports, minutes of meetings could be acceptable or the assessment could be part of the management review. Context changes should be input for the review (see 9.3). If there is no documented evidence, an interview with the top management could provide indications as to how the internal and external issues, leading to an understanding of the context in which the organisation operates, have been taken into account. The auditor should verify and assess consistency of the context determined by the organisation, risk analysis and planning of the quality management system. If the analysis appears incomplete or superficial, it should be determined whether this could constitute a real hazard in terms of the organisation's ability to meet the implicit/explicit requirements of customers, mandatory requirements, and as a consequence, formalise a finding.
4.2 Understanding the needs and expectations of interested parties	
This point is completely new compared to the previous ISO 9001:2008. The organisation shall determine which interested parties may influence its ability to continuously provide products and services which meet the implicit, explicit and mandatory requirements. The expectations of the interested parties, which may influence the quality management system, shall be identified. It is to be noted that a complete analysis of all interested parties is not required, only of those relevant to the quality management system, that is to say, which could have a potential impact on the effectiveness of the system in relation to the context in which the organisation operates or intends to operate. Consideration of the needs of interested parties shall be functional to customer satisfaction. Examples of interested parties can be: - end users of products, who may have different	It is not explicitly required to have documented evidence of this analysis, but it could be reasonably expected that this information be contained in a document, reviewed and updated periodically (see 4.1).

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
expectations compared to the specific requirements of the direct customer; - shareholders, who through their policies influence the management system with repercussions on product quality; - employees and unions, management of working hours, claims concerning safety with a request to invest in infrastructure; - external providers, need to meet payment terms for reciprocal sustainability, need to plan orders to comply with delivery deadlines. The requirements or expectations of interested parties shall be input for quality management system (see 6.1) and management review planning (see 9.3).	
4.3 Determining the scope of the quality management system	
The scope of the quality management system determines the boundaries within which the requirements of the standard apply. The scope shall be documented and shall identify the products and services included under the management system, even if it is no longer necessary to draw up a "quality manual" and it shall be subject to periodic review. What is to be taken into account to define the scope is now explained: the internal and external issues and requirements of interested parties as well as, of course, the products or services offered by the organisation. The standard no longer talks about exclusions but rather about applicability of requirements, establishing that if a requirement is applicable, it shall be applied. All the requirements of the standard relevant to the scope established by the organisation apply. If a requirement cannot be applied, this shall not affect the organisation's ability and/or responsibility to ensure conformity of the products and services and customer satisfaction. Also justifications related to non applicability shall be documented and above all, it is necessary to demonstrate that any non-applicable requirements do not affect the system, products or services offered, also through a risk analysis (see 6.1). Due attention is to be given to the term "responsibility", which considerably affects also externally provided processes or products: the organisation cannot be exempted from responsibility for the results of these processes and/or products.	A thorough analysis of the accuracy of the quality management system scope is fundamental: it is to be in line with customer requests and with mandatory requirements. Consistency with the internal and external context in which the organisation operates and with the requirements of interested parties are also to be checked. It should be checked that all products/services under the certification scope are covered by the quality management system and any non-applicability of requirements should be supported by a pertinent analysis. In particular, it is necessary to check that the organisation assumes responsibility for externally provided processes (see 8.4.2). Examples of critical cases: - design externally provided by an engineering company; - a product subject to mandatory requirements (food products, medical devices) manufactured externally; - hospital nursing care assigned to a cooperative; - externally provided school refectory services.
4.4 Quality management system and its processes	
This requirement already exists under point 4.1 of ISO 9001:2008. Greater emphasis has been given to the process approach, to the measurement of the effectiveness of the processes and to	As an alternative to the quality manual, flow charts or tables, responsibility matrices, procedures or other equivalent documentation could be made available. It should be checked that the indicators determined by the

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
continuous performance improvement. In particular: - the inputs required and the outputs expected from each process, their interaction and the resources needed for these processes shall be determined; - the methods, criteria and indicators which measure process performance shall be determined; - the responsibilities and authorities for the management of these processes shall be assigned. ISO 9001:2015 includes an additional requirement: - the risks (understood as threats) and opportunities shall be addressed, as well as their management (see 6.1). A specific point (see 8.4) deals with control of externally provided processes; these processes shall, in any case, be described in the process flow, including an analysis of the risks and opportunities. It is no longer necessary to prepare the 6 documented procedures on some aspects dealt with by the standard but the organisation is required to retain documented information (procedures) supporting the operation of its processes, to the extent considered necessary. The quality manual is also no longer mandatory but an organisation which already has one may decide to keep it and update it according to the new requirements. Moreover, documented information (records) is to be retained and made available to provide evidence that the processes are being carried out as planned.	organisation are suitable to measure the effectiveness of the processes in relation to the outputs expected from each process. With reference to the need to retain documented information supporting the processes, it should be checked that the management system is able to meet the requirements of the standard and that the organisation is able to operate and ensure product conformity using the documentation prepared. How the organisation, in developing and implementing the system, has taken into account actions addressed to manage risk relating to each process should be evaluated.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
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5 Leadership	
5.1 Leadership and commitment	
5.1.1 General	
The responsibilities of the top management and its role have been emphasised, in terms of support and motivation relevant to human resources and quality management system implementation. The new standard no longer mentions a Management Representative but explicitly involves the “Top Management”. In this connection, it is to be noted that the new standard introduces the concept of top management as: <i>“Person or group of persons who direct and control an organisation at the highest level”.</i> Firstly, it is in fact the top management who should demonstrate awareness of the importance of a quality management system. Top management involvement is fundamental for the effective implementation of a quality management system and it is recalled in many standard requirements. The requirements mentioned in points b and c make the concept of integration between the “organisation’s business processes” and the quality management system more explicit. Implementation of an organisation’s business processes also extends to processes linked to business in line with the organisation’s objectives and performance. The need to promote use of the process approach and of risk-based thinking is more explicit.	Compliance with the requirement of the standard could be checked through: a. a talk with the Top Management to assess its actual commitment; b. management review verification; c. verification of strategic objectives and direction; d. interviews with the personnel; e. verification of top management communications; f. actual availability of suitable resources; g. verification of actual personnel involvement. Definitions of strategies and objectives related to the following should be available: - business of the products/services which are the subject of the scope of the system; - compliance with customer requirements also taking into account relevant interested parties; - any applicable mandatory requirements. Moreover, the following should be assessed: - evidence that the objectives have been stated within the organisation; - evidence of monitoring activities and verification of the state of implementation of the defined objectives.
5.1.2 Customer focus	
In general, the concept of top management involvement in the determination of direct and indirect customer requirements remains. The point of the standard includes a specific reference also to “statutory and regulatory requirements” and to the need to determine the risks and opportunities, referred to compliance with customer requirements and applicable statutory and regulatory requirements.	Evidence should be sought in the definition of the quality policy, strategies and objectives and in the risk analysis (see 6.1). Evidence could be sought, for example, in: - the minutes of meetings held by the top management with customers; - results of market and competitor research; - data analysed during management reviews. In particular cases, as for example: - entry in a new market - addressing a new customer - new or substantial changes to a mandatory requirement, the top management could activate risk analyses (see 6.1) and related opportunities. Finally, verification of the effectiveness of the tools prepared may, in any case, be demonstrated through results, in terms of customer satisfaction/dissatisfaction (performance analyses by

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
	means of indicators, complaint analyses, returns, etc).
5.2 Policy	
5.2.1 Establishing the quality policy	
The new aspect consists in making reference to the context in which the organisation operates and communicating it to relevant interested parties. In relation to the new edition of the standard, it can be said that the period of generic and static quality policies is definitely over. The contents of the policy should be consistent with the results of the context analysis, requirements of customers, other interested parties and applicable mandatory requirements and the established objectives should be in line with the policy. Continuous changes to the organisation and to the context in which it operates necessitate a periodic review of the policy.	It should be ascertained that the policy is in line with: - the analysis of the context - customer needs and expectations - the organisation's strategies - any mandatory requirements - the needs and expectations of other relevant interested parties and that the established objectives are consistent with the policy. The policy should contain a commitment towards continual improvement of the quality management system.
5.2.2 Communicating the quality policy	
In terms of communication, the quality policy should be made available, not only within the organisation but also to relevant interested parties, in order to promote their involvement. The policy could be made available using any means.	It is necessary to verify that the policy is available as documented information, has been appropriately communicated within the organisation and consequently is understood and applied. It is advisable to check whether, how and on the basis of which criteria the interested parties to whom the policy may be made available have been identified and if, therefore, it has been communicated to the outside (for example, it could be divulged to external providers who, through their work, contribute to the organisation's success). Lastly, it should be verified that the policy is revised in synchrony with the re-assessment and changes to the context.
5.3 Organisational roles, responsibilities and authorities	
An organisation's top management is required to define the responsibilities and authorities related to the processes and activities carried out. Even though the requirement of the standard does not refer to documented information, there may be different ways of defining responsibilities and authorities, which depend on the practices in use and in any case on organisational complexity. The role of Management Representative, who was responsible for running the quality management system, is no longer foreseen but these responsibilities and authorities are nevertheless required to be assigned. The top management communication channel, within the organisation and to the outside, concerning the quality management system should be clearly defined, through the assignment of the pertinent responsibilities. The responsibilities and authorities assigned, also to more than one person, and for which they are competent, are to be communicated and known within the organisation. Elimination of the requirement related to the Management Representative does not necessarily involve cancelling this	In most cases, organisation charts, organisational documents, job descriptions should be available. However, depending on the complexity of the organisation and of its activities, a definition of responsibilities may be acceptable, at the following level: - process flows; - management procedures; - operational instructions; - restricted access to the organisation's IT system. However, it is always advisable to check the actual relevance of the figures to whom responsibilities and authorities have been assigned as well as consistency between the latter and those actually noted during the audit in connection with organisational processes.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
role from the quality management system, particularly in cases where delegation is not formal but more substantial and/or functional, as well as to represent the Top Management, for example vis-à-vis customers.	

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
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6 Planning	
6.1 Actions to address risks and opportunities	
Although the standard does not specifically talk about “risk analysis”, a “risk based thinking” approach is considered fundamental to plan a quality management system, considering that one of the aims of the system is to provide a prevention tool for the organisation which adopts it. Even if the word “risk” is normally considered negative, it may have either a positive or negative connotation. Risk management is specifically required in relation to the following: - quality management system and its processes (see 4.4.1,f) in terms of determination of risks and opportunities associated with the processes; - customer focus (see 5.1.2,b) in terms of risks and opportunities which may affect the organisation’s ability to enhance customer satisfaction. Moreover, from the text of the requirement, the following can be deduced: - post-delivery activities (see 8.5.5) in terms of risks and opportunities associated with the products and services. Opportunities can include, for example: launching new products, opening new markets, using new technology, building partnerships, etc. Lastly, among the management review inputs (see 9.3), the effectiveness of actions taken to address risks and opportunities is also taken into account. When planning the quality management system, it is necessary to refer to the results of the context analysis (internal and external) in which the organisation operates, as well as to the results of the analysis of requirements of relevant interested parties. Bearing in mind the above, it is necessary to identify the risks and opportunities linked to achievement of the intended results and identify the events which could interfere with achievement of the objectives or which could represent improvement opportunities. It is to be noted that the standard does not require an analysis to be carried out according to a specific model (an organisation is free to choose the most appropriate approach or methodology to meet the requirement) or even a “formal” documented process for risk management; however, minimum documented evidence could be useful to keep the pertinent activities under control. In particular, organisations shall: - analyse and classify risks in relation to the seriousness of possible consequences;	It should be possible for the auditor, starting from the system’s objectives which are to be documented (6.2.1), to trace back the actions planned to achieve these objectives (6.1.2) and, through interviews and other “documented information” (for example, management reviews), check whether these actions are in line with and appropriate for the objectives and, moreover, whether they are appropriate in relation to the risks and opportunities identified. It should be verified whether the organisation applies risk analysis techniques, (as for example FMEA of design, process, and product). In connection with risk analysis, it is to be hoped that organisations identify suitable methods to make a hierarchy of risks as, for example, indexes based on the seriousness (of the consequences) and on the probability of events occurring. Furthermore, it should be checked whether the organisation has identified/planned the need to review its actions. It should be checked whether the organisation’s personnel is aware that the approach to the quality management system and its processes is based on risk-based thinking.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
- plan actions to address these risks (their elimination and/or mitigation); - implement these actions; - evaluate their effectiveness; - learn from experience. In classifying risk, it may be useful to refer to internationally recognised methods (e.g.: ISO 31000, or others). However, the organisation is responsible for establishing to what extent and how to manage a risk analysis in connection with its quality management system, taking into account the type of product, its complexity, critical processes and in general, the context in which it operates. ISO has published an interesting document (Annex 3) in which it explains how to address the risk-based thinking approach in developing a quality management system. The document also includes examples which, though very simple and basic, make it possible to understand how organisations, even the least complex ones, bearing in mind the context in which they operate, can adopt and follow risk-based thinking when planning and developing their own system. The results of the risk analysis should be used to plan the quality management system, in all its phases. In particular, the organisation should define the identification of the methods to keep the processes under control, using risk-based thinking. For organisations, it could be an opportunity to review what has been done in the light of greater efficiency. In the case of organisations which already implement risk analysis techniques, as for example FMEA of design, process, product, these may be taken into account, the need to extend the analysis to other contexts being understood. A non-exhaustive list of possible risks an organisation could assess in relation to the context in which it operates is given in an annex (see annex 4). However, it is to be noted that not all processes determined for the quality management system may present the same level of risk and the risk level could be different depending on the needs of the various customers. A risk analysis should sometimes be reviewed, updated or repeated and, in any case, whenever considered necessary. The need to perform and/or review a risk analysis may arise in the following cases: - results of the context analysis; - results of the analysis of the needs of customers and other relevant interested parties; - results of the analysis of compliance with mandatory requirements; - definition and/or revisiting of processes; - any other need, as for example the choice of a new external provider, extension of an instrument's calibration period, the need to reduce sampling during quality control stages, etc.	

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
Another issue, which should be taken into account, concerns training in risk analysis techniques.	
6.2 Quality objectives and planning to achieve them	
The requirements remain essentially the same as those in ISO 9001: 2008; however, more details are given concerning the expected characteristics for the objectives and the second part of the requirement specifies how to plan the objectives. The need to define real and measurable objectives, concerning or derived from the following, is confirmed: - organisation's strategies; - market analyses; - customer requirements; - mandatory requirements; - analyses of processes; - risk analyses; - etc. The objectives can then be developed in more detail, involving the organisation's pertinent levels and relative functions. A significant new element compared to the previous edition of the standard concerns the request to establish qualitative objectives for products and processes and to enhance customer satisfaction. The concreteness of the objectives is also a function of their real and specific planning for relative achievement.	Compliance with the requirement could be checked through one or more of the following aspects: - documented evidence of the definition and communication of the objectives, verifying their consistency with the results of the context analysis, the quality policy, customer requirements and applicable mandatory requirements; - consistency between the detailed objectives and the macro and/or strategic ones; - evidence of what has been planned to achieve the objectives; - assignment of responsibility and resources to achieve the objectives; - what has been put in place by the organisation to keep achievement of the objectives under control.
6.3 Planning of changes	
There are no substantial new elements to the requirement but it is more detailed. Implementation of the requirement requires organisations to check, in the case of changes, as for example: - introduction of new products; - introduction of new markets and/or customers; - amendments to contractual requirements; - amendments to mandatory requirements; - organisational changes; - changes to or introduction of new IT systems; their impact on the quality management system.	Compliance with the requirement could be assessed by checking whether any changes have had an impact on the quality management system and how they have been planned and managed.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
7 Support	
7.1 Resources	
7.1.1 General	
The organisation shall determine and provide the human and infrastructural resources, in-house and external, needed to manage the processes which come under the scope of the quality management system. To identify what is needed, the organisation shall take into consideration the capabilities of and constraints on existing internal resources and the need to involve also external resources in order to comply with customer requirements and expectations and to develop the new business activities identified.	The management review (see 9.3.1) should include evidence of an analysis of the resources necessary and of the relative actions to be taken to fill any gaps. It should be possible to verify for every process that: - adequate in-house and external human and infrastructural resources have been allocated, in line with the established objectives; - the performance indicators, return on investment and the need to acquire resources in view of a substantial change (see 9.3.2) to the product or service have been defined. It should be checked whether, to determine resources, the potential impact of externally provided processes and/or activities (products, components, materials, services, processes, ... other) has been taken into consideration.
7.1.2 People	
The organisation shall provide the personnel necessary for the effective implementation of its quality management system and for the operation and control of its processes so as to continuously meet customer requirements and the applicable statutory and regulatory requirements. For example: - in the case of a contract requiring the employment of a minimum number of people for a given activity; - if completion of an activity is to be guaranteed by a certain date in order to pass to the next process.	The organisation should be able to demonstrate that the people identified are suitable for the needs of the quality management system and for the established objectives. Any clauses concerning the number of people needed for the activity, established contractually with the customer, should be verified.
7.1.3 Infrastructure	
To ensure the adequacy and effectiveness of its infrastructure, the organisation shall provide suitable work instructions, taking into account appropriate user competency and programme routine maintenance works.	Compliance with the requirement could be checked through: - an analysis of the infrastructure needs based on the plan of objectives; - assessment of external providers used; - examination of the maintenance programme and plans foreseen to control the infrastructure and relative records of the checks made considering also the mandatory checks (in relation to the quality of the product/service provided); - verification of external provider contracts for maintenance services.
7.1.4 Environment for the operation of processes	
Note that the generic term environment and not work environment is used. This generality extends the reference from the technical and infrastructural structures, combining human and physical	It should be checked whether the organisation has considered and determined which social, psychological and physical factors are relevant in connection with producing the product/providing the service.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
factors. The environment includes all types of variables which could influence the wellbeing and behaviour of people who have direct or indirect relations with the organisation.	Compliance with the requirement could be checked through: - an analysis of the environmental conditions adapted to the needs of the organisation; - examination of the control plan of the work environment conditions and the records of the checks and monitoring carried out considering also the mandatory ones (in relation to the quality of the product/service provided) and qualification of the external providers used; - examination of contracts with external providers of maintenance services.
7.1.5 Monitoring and measuring resources	
7.1.5.1 General	
7.1.5.2 Measurement traceability	
As in the previous edition of the standard, monitoring and instrumental and non-instrumental measurement cases are foreseen, using different means (measuring and monitoring resources, testing, telephone inquiries/questionnaires). The organisation shall determine the resources needed, human and infrastructural, involved in the monitoring and measuring processes, to ensure valid and reliable results and, where required, metrologically traceable. The organisation shall ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken, are maintained to ensure their continuing fitness for their purpose and shall retain appropriate documented information as evidence.	Compliance with the requirement could be checked through: - examination of procedures or work instructions which provide evidence of planning of the resources needed to perform valid and reliable monitoring and measurement activities; - examination of monitoring and measurement records. These documents are to be available (documented information). Among these, also learning efficiency tests for training companies may be considered, for example; - calibration records, management and control of monitoring and measuring resources (for example, records of tests performed); - examination of the opinion of adequacy of the external provider used, if this activity is provided externally.
7.1.6 Organisational knowledge	
This new requirement focuses on the importance of maintaining availability, within the organisation, of adequate knowledge to achieve conformity of products and services and of determining its availability if lacking. It emphasises the need to capitalise the organisation's experience to increase the personnel's knowledge in order to ensure conformity of products and services and the organisation's need to be able to adequately address the changing internal and external context in which it operates, as well as customer and interested parties' expectations. The organisation shall assess how its knowledge is determined and protected and consider how to acquire the necessary knowledge for everyday use and for the future, using both internal and external sources. The means to identify, maintain and protect competency/knowledge can be derived from: - failures or successful projects; - contributions in terms of value of individuals within the organisation relevant to experience, knowledge and skills; - exchange of experience with customers, external providers and partners.	Compliance with the requirement could be checked through: - analysis of any documents which identify the sources and type of knowledge necessary (i.e.: management reviews); - evidence that an assessment of knowledge has been made before any change to the management system or following the need for specific changes; - reconstruction, also through interviews, of an actual case of change.
NOTE KNOWLEDGE: Acquisition of contents, that is to say,	

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
<i>principles, theories, concepts, terms, rules, procedures, methods and techniques.</i>	
7.2 Competence The concept expressed in the standard is that the competence necessary for each activity to be carried out shall be determined and that the people who carry out the activity have the necessary competence. NOTE COMPETENCE <i>Utilisation of knowledge acquired to resolve situations or produce new products/services</i> It is to be noted that competence can be acquired in many ways and is not strictly connected with training; training is only one aspect to be considered. It is necessary to also determine the competence required of the people doing work <u>under the organisation's control</u>, external to the organisation (e.g. external providers).	Compliance with the requirement could be checked through: - identification and analysis of the necessary competence, also in the case of changes; - Management Review with risk assessment (identification, confirmation, updating of competence, request of new competence for new business); - verification of any personnel development plans and related objectives; - verification of any competence development plans; - verification of any competence monitoring plans; - corrective actions; - examination of the outcome of internal audits to evaluate new competence or competence to be updated; - examination of records of training activities performed and verification of their effectiveness.
7.3 Awareness The requirement states more specifically what the personnel shall be <u>aware of</u>, focusing attention on the quality policy, quality objectives, the contribution of each person to the effectiveness of the management system and to the benefits associated with enhanced performance and the implications/repercussions of nonconforming situations relative to the management system. "Awareness" becomes a requirement. The requirements in point 7.3 are not only aimed at the organisation's personnel but also at external providers and external parties. The requirement necessitates a guarantee that the personnel operating within the organisation, also personnel not directly employed but involved in the organisation's processes, is aware of the importance of its work as a contribution to the effectiveness of the management system. The requirement focuses attention on the implications of a nonconformity occurring (consequences on the management system, on the product/service provided to the customer, on internal and external customers, etc.). The methods to bring about employee awareness can vary and can include: - direct communications; - meetings; - management system audits; - specific training; - sharing of objectives/results; - sharing of NC found; - sharing of the contents of the quality policy; - awareness questionnaires; - any instructions/procedures.	The auditor should assess personnel awareness during the verification of process management and development as it forms an integral part. During the audit, the organisation's implementation of this requirement could be assessed, for example, through direct interviews, checking of records, etc. Interviews with the personnel, throughout the audit, could be one of the most important methods to check awareness acquisition, (see also point 5.1) and thus the effectiveness of what the organisation has implemented to meet the requirement. The examination of records could provide support also to verify implementation of the requirement, particularly in the case of processes provided externally.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
7.4 Communication This requirement is more detailed compared to the previous edition of the standard and introduces the concept of external communication with interested parties. The organisation shall determine the internal and external communications to be made, by whom and to whom, how they are to be made and when, the responsibilities and authorities. The top management shall ensure communications are sent out at all levels, clearly, understandably and in line with the objective; external communications enable the needs and expectations of relevant interested parties to be understood and met.	During the audit, the organisation's transposal of this requirement could be assessed, for example, by verifying management of internal and external communications, checking assignment of responsibility for communications also through interviews with the people concerned and analysis of the different types of information communicated. The internal and external communication channels should be verified as well as the relative responsibilities, in relation to the context in which the organisation operates and the organisation model under review (for example, mandatory sector, corporate model, units distributed worldwide, temporary sites, yards ...).
7.5 Documented information 7.5.1 General	
"Documented information" replaces the terms record and documented procedure, present in the previous editions of the standard. This concept is one of the main innovations of the new edition of the standard, contributing in a decisive way to the simplification of the documental requirements. The organisation shall determine which documents are necessary for the management and effectiveness of the system and how they are to be managed. Point A.6 (Appendix A to the standard) clarifies that: - "retain documented information" refers to those documents which the previous edition of the standard indicated as "records"; - "maintain documented information" refers to those documents which the previous edition of the standard indicated, for example, as manual, documented procedure, instruction, quality plan, etc. which require controlled management and are needed to manage the system. The standard clearly indicates for which requirements it is necessary to retain documented information or maintain documented information.	The documented information specifically required by the standard is as follows. - Scope (see 4.3) (including any justifications for non-applicability of the requirement). - Description of the quality management system and its processes (see 4.4). - Quality policy (see 5.2.2). - Quality objectives (see 6.2.1). - Adequacy of the monitoring and measuring resources (see 7.1.5). - When measurement traceability is a requirement, the calibration or verification methods; if there is no such standard, the basis used for calibration or verification is to be indicated (see 7.1.5.2). - Competence (see 7.2). - Demonstration of conformity of the process as planned and of the product to the requirements (see 8.1). - Review of the requirements for products (see 8.2.3). - Design and development inputs (see 8.3.3) - Design and development controls (see 8.3.4). - Design and development outputs (see 8.3.5). - Design and development changes (see 8.3.6). - Documentation on the evaluation and monitoring of performance of external providers (see 8.4.1). - Definition of the characteristics of the products/services and the results to be achieved (see 8.5.1). - Activities to be performed and results to be achieved (see 8.5.1). - Identification and traceability (see 8.5.2). - Property of a customer or external provider is lost, damaged or found unsuitable for use (see 8.5.3). - Control of changes (see 8.5.6). - Evidence of conformity with the acceptance criteria of the product/service released (see 8.6).

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
	- Traceability to the person(s) authorising the release of the product/service to the customer (see 8.6). - Control of nonconforming outputs of processes, products or services (see 8.7). - Evidence of the results of monitoring and measurement, analysis and evaluation (see 9.1.1). - Evidence of implementation of the internal audit programme and relative results (see 9.2.2). - Management review outputs (see 9.3.3). - Nature of the nonconformities, subsequent action taken and corrective action (see 10.2.2). It could be checked whether the organisation has determined the following documentation as necessary: - documented information of external origin determined by the organisation (see 7.5.3.2); - design planning.
7.5.2 Creating and updating	
Essentially, there are no differences compared to the previous edition of the standard. When creating and updating documented information, the organisation shall ensure appropriate identification and description, format and adequacy through suitable review and approval. Examples of acceptable methods are given.	Compliance with the requirement could be checked through: - examination of the different types of documented information implemented, their management including the updating status.
7.5.3 Control of documented information	
Essentially, there are no differences compared to the previous edition of the standard. The documented information required by the quality management system shall be controlled to ensure it is available and suitable for use, where and when it is needed, and adequately protected (i.e.: from loss of confidentiality, improper use or loss of integrity). For the control of documented information, the organisation shall address distribution, access, retrieval and use, storage and preservation, including preservation of legibility and control of changes (version control), retention and disposition. There is no direct reference to retention time; reference is made to retrieval. Documented information of external origin necessary for the planning and operation of the quality management system shall be appropriate and controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations.	Compliance with the requirement could be assessed by examining how the documented information is managed. Compliance with the requirement could be assessed through: - examination of implementation of the methods of management, control and protection of documented information; - examination of the identification and updating methods of documented information of external origin; - examination of any list of documented information with the updated status; - access to and use of any electronic systems used to control documented information.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
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8 Operation	
8.1 Operational planning and control	
This is a general requirement to be incorporated in each operational process, to the extent necessary in relation to the organisation's characteristics and scope of its quality management system, taking into account what has been planned to ensure achievement of the objectives and prevent/reduce risk.	How the organisation has planned the operational activities should be checked. For operational planning, the organisation should provide evidence of how it has planned "<u>control</u>" of operational activities. In the case of operational management, the following should, for example, be checked: - quality plans; - quality control plans; - design plans; - product manufacture /service provision plans; - work cycles; - planning of resources; - list of materials. With regard to operational control (to be found within the relative operational process) of the product/service: - control points, validation, monitoring, measurement, testing, qualification, specific inspection and testing for the product/service. At process management level: - validation, monitoring, measurement, risk analysis. It should be checked whether there is documented information, related to both programming and records, which provides evidence of the above.
8.2 Requirements for products and services	
8.2.1 Customer communication	
One or more processes to manage customer communications are to be determined. These need not all be separate processes; some could be verified through actions within operational processes. Different customer communication management stages can be identified: - contacts with the market (information about the product and service through brochures, web, visits, etc, market feedback); - contacts during the quotation and order review phase (information concerning the product and service, enquiries, definition of contracts or orders); - contacts during management of the order, including support when contractually established (enquiries, handling of contracts/orders, including relative updating, customer feedback, including any complaints, handling of customer property when applicable, specific requirements for contingency actions, when relevant); - contacts during delivery and post-delivery.	The method implemented to achieve effective customer communication, including responsibilities and authorities, should be checked. Clarity of the communication in relation to the subject and objective should be checked, avoiding any ambiguity so as not to create false expectations. The replies to the communications should be checked, as far as applicable, in terms of effectiveness and response time. How information, broadly speaking, to the market is kept under control should be verified, for example through: - brochures - web site - catalogues - advertising - labelling and packaging - product's instructions for use - services charter - training offer plan - offers / confirmation of orders - etc.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
8.2.2 Determining the requirements for products and services	
This requirement already exists in ISO 9001:2008. The organisation shall ensure that: - the requirements for the product/service are defined in full; - it is able to meet the requirements defined for the product/service it offers; - it can meet the claims for the products and services it offers. Possible cases: - standard products (products whose characteristics have already been completely defined at regulatory level); - catalogue products/services (design already performed and validated by the organisation); - catalogue products/services but with changes required by the customer (design to be partly revised); - new products requested by the customer (design to be entirely developed).	Compliance with the requirement could be checked by: - evaluating if and how market information is received and managed; - evaluating how the mandatory requirements are managed and taken into account in internal documents and in the product/service; - evaluating how communications with potential customers are handled; - evaluating how the organisation re-examines the requisites offered to potential customers; - evaluating if the information (instructions, advertising, web site, etc.) related to the characteristics of the products and services offered is sound. It should be checked how the organisation is able to ensure compliance with the requisites offered through: - evidence of suitable resources (in-house or external), including external providers; - existence of a programming system suitable for the product/service to be offered; - existence of methods to review the requirements related to products and services (among which the order and contract review); - effective compliance with the requirements defined for the products, processes and/or services.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
8.2.3 Review of the requirements for products and services	
The organisation is required to conduct a review of the requirements indicated by the customer (during the request for offer, order and order review stages) to ensure it has the ability to provide what the customer requires. If the customer does not specify the requirements, the organisation shall specify them and communicate them to the customer (in the offer or order confirmation). Situations in which a formal review for each order is impractical are also to be taken into account (for example, internet sales). Requirements from interested parties come under the category of requirements considered necessary by the organisation for customer satisfaction (use of products or materials with less environmental impact, use of external providers mindful of corporate social responsibility, etc.). Documented information (records) is to be retained.	The availability of documented information related to review activities (offer, order/contract, order review) should be verified and whether it is sufficient to provide evidence of its correct execution, also checking that it has been done prior to provision confirmation. It should be verified that the product requirements, including delivery method and post-delivery activities, correspond to what is indicated in the offer, order and/or order confirmation. If formal review of the order is impractical (for example internet sales), verification should concern information related to the products, such as catalogues and advertising material.
8.2.4 Changes to requirements for products and services	
When the requirements for products and services are changed, the organisation shall ensure that relevant documented information is amended and that relevant persons are made aware of the changed requirements.	Some examples of managing a change should be checked.
8.3 Design and development of products and services	
8.3.1 General	
The design and development process shall be such as to ensure the provision of products and services. The design and development results are the characteristics that the product/service shall have to meet the specified requirements.	Adequacy of what the organisation has determined in relation to the type of product, process or service provided and its requirements should be checked.
8.3.2 Design and development planning	
The stages and controls for design and development are to be determined. The requirement is more detailed and in particular there is the possibility to involve the customer in the design stage.	How the organisation has adequately planned the design and development activities should be checked. It should be checked that, to determine the stages and keep the design and development process under control, the documented information, necessary to confirm that the design requirements have been met, has been taken into consideration.
8.3.3 Design and development inputs	
The standard gives a series of factors to be taken into account to determine the design input data. Among the codes of good practice, also the information derived from previous similar design and development activities, as well as nonconforming situations and complaints originating from previous designs should be	How the organisation determines the design and development input requirements should be verified. Availability of records of design and development data input should be checked.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
considered. With reference to the requirement in point e), the organisation shall take into account the outcome of the analysis of the potential consequences of failure due to the nature of the products and services.	
8.3.4 Design and development controls	
This requirement already exists in ISO 9001:2008. No important considerations, as it is essentially the same as in the previous standard.	What the organisation has planned, to keep the design process under control, should be checked. It should be possible to check the retained documented information on reviews, design verification and validation and on any action taken to resolve problems determined during these stages.
8.3.5 Design and development outputs	
Compared to the previous edition of the standard, what is required under point c) has been added, which makes explicit reference to the monitoring and measuring requirements. In any case, the product/service monitoring and measuring criteria were already a design output.	What the organisation has planned to meet the requirement should be checked for adequacy. It should be verified that the documented information related to the design and development process outputs is adequate for use of the product/service and provides evidence that the relative requirements have been met.
8.3.6 Design and development changes	
Compared to the previous edition of the standard, no significant changes have been made. Availability of documented information on authorisation of changes and on the actions taken to prevent adverse impacts is explicitly required.	It should be verified that the documented information on design and development changes, including authorisation of changes and their justification, as well as the actions taken to prevent adverse impacts is adequate and provides evidence that the relative requirements have been met.
8.4. Control of externally provided processes, products and services	
8.4.1 General	
Externally provided processes and services are now explicitly included. The organisation shall ensure that what is externally provided conforms to requirements. Cases where it is necessary to determine controls on externally provided products and services have been more clearly defined. Monitoring of performance of external providers has been made clear. It is explicitly required that documented information related to the evaluation of external providers be retained.	Compliance with the requirement could be assessed, by verifying the criteria determined for the choice of controls to be applied to externally provided products, processes and services. Compliance with the requirement could be assessed through: - verification of the criteria determined for the choice of external providers, in line with the assessment of risk/opportunities; - verification of the criteria determined for monitoring and periodic review of the performance of external providers according to type of external provision (for example, difference between external providers of services and products); - verification of the documented information on initial evaluation of external providers and their re-evaluation; - verification of the handling of nonconformities, complaints and remarks concerning external providers.
8.4.2 Type and extent of control	
Determination of the criteria is more detailed but there is no significant change compared to the previous edition of	Compliance with the requirement could be assessed through: - verification of the criteria determined for the choice and

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
the standard. It is made clear that if a process is entirely provided by an external provider, it shall remain under the control of the organisation's quality management system. The type of controls the organisation applies to the external provider and to the resulting output shall, in any case, be defined by the organisation. The control plan is not expressly required to be documented information. However, even if there is nothing written, the personnel responsible for the controls should clearly know what to do. In reality, for some products, a control plan for external provision is specifically required by other applicable documents (i.e. CE marking standards and STC Guidelines for pre-packaged concrete, contractual standards such as IFS and BRC in the food sector).	extent of the controls to be applied to externally provided products, processes and services, consistent with an assessment of risk/opportunities, including customer specifications and the need to guarantee continuity of activities; - verification of any control plan; - verification of any records of controls; - interviews with the personnel responsible for the controls; - evidence of controls related to externally provided processes (monitoring, second party audits, etc.) in relation to the impact on product/service conformity; - verification of consistency between type and extent of controls and purchase contracts/specifications; - evidence of external provider planning and execution of controls.
8.4.3 Information for external providers	
There is no significant change compared to ISO 9001:2008. It has been clarified that adequacy of the requirements shall be ensured prior to their communication to the customer. The only novel aspect is point e), even if it is obvious that an external provider will, in some way, expect to be controlled and monitored. No documented information is required; however, it is unlikely that an organisation will not retain any documented trace in connection with this aspect.	Compliance with the requirement could be assessed through: - verification of how the purchase orders and contracts are defined/approved; - verification of communication methods identified with the external providers and completeness of the information provided; - examination of purchase orders; - examination of contracts (specifications).
8.5 Production and service provision	
8.5.1 Control of production and service provision	
This requirement necessitates the availability of documented information, which defines the activities to be performed and the results to be achieved. Control requirements have been extended to release, delivery and post-delivery activities of the product and service. Documented information is explicitly required and is to contain the activities to be performed and the results to be achieved. The main novelty is the requirement to implement actions to prevent human error.	Compliance with the requirement could be assessed through: - examination of work instructions, also in "simplified" form, such as tables, images, flow diagrams; - examination of any control plans, including acceptance limits; - examination of records of controls carried out; - examination of documented information on any processes which have to be validated and relative validation evidence; - identification of situations in which human error may have an impact on product/service conformity and of the definition of prevention and/or containment measures implemented.
8.5.2 Identification and traceability	
There is no significant change compared to ISO 9001:2008.	Compliance with the requirement could be assessed through: - verification of the criteria determined for identification and traceability, consistent with the contractual conditions and/or mandatory requirements; - verification of the criteria determined for identification and traceability, consistent with the assessment of risk/opportunities;

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
	- verification of the existence of complete information for identification and traceability management; - evidence of traceability tests performed by the organisation; - verification of any physical identification and traceability methods.
8.5.3 Property belonging to customers or external providers	
Compared to the previous edition of the standard, the requirement covers the property of external providers. Documentation of external origin belonging to the customer or external provider shall be treated in accordance with these requirements (see 7.5.3). The note gives examples of a customer's or external provider's property.	Compliance with the requirement could be assessed through: - observation of activities, method of managing/preserving customer/external provider property; - verification of controls of incoming materials provided by the customer/external provider; - verification of communications with the customer/external provider; - verification of personal/sensitive data handling; - verification of customers' intellectual property management.
8.5.4 Preservation	
There are no significant changes compared to the previous edition of the standard. The word "product" has been replaced by "process outputs"; however, in the 2008 edition it talks about "during internal processing". In the 2015 edition, the word "delivery" has disappeared but returns in the note as "transportation". In fact, the two variations compensate one another and the meaning is that preservation is to be ensured during all stages of the production process and extended to the stages related to the process of transmission, transportation, delivery, as well as preservation at the point of sale when these are under the organisation's responsibility.	Compliance with the requirement could be assessed through: - verification of management methods for raw materials, semi-finished products, products; - existence of indications on how to manage products: work instructions, storage methods in the warehouse, etc.; - verification of packaging and dispatch methods; - verification of preservation conditions, including any contamination, during the stages of the entire process under the organisation's responsibility.
8.5.5 Post-delivery activities	
In relation to the responsibilities associated with an organisation's products and services, the requirement, innovative, extends the activity area to be considered up to the inclusion of undesired consequences associated with the products/services; the use, nature and intended lifetime of the product and service; customer feedback; contractual obligations in terms of warranty, maintenance obligations, recycling or final disposal and similar.	Compliance with the requirement could be assessed through: - verification of criteria to determine the extent of post-delivery activities, in line with the assessment of risk/opportunities and customer needs; - verification of contractual and warranty conditions; - verification of communications with customers following delivery and which are not only replies to complaints.
8.5.6 Control of changes	
It is necessary to define the tasks and responsibilities concerning how to manage changes, both when they are planned and in "unforeseen" situations when it is not possible to adopt the methods defined for production of the product or provision of the service.	Compliance with the requirement could be assessed through: - verification of the methods determined (including responsibilities and authorities) for the definition and approval of the production processes/service provision; - verification of any risk analysis carried out to validate the choices made; - verification of documentation relevant to any critical situations;

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
	- verification of the definition of roles for critical situations in documented form or through interviews with the personnel (if a problem needs to be solved, who should be called?).
8.6 Release of products and services	
There are no significant differences compared to ISO 9001: 2008. Evidence of conformity with the acceptance criteria is to be retained as well as documented information on authorisation of release of products/services to customers.	Compliance with the requirement could be assessed through: - verification of methods defined for authorisation of release of the product/service and relative supporting documented evidence; - examination of records of the controls carried out with the results of the checks performed in relation to the acceptance criteria; - examination of the product's conformity declaration; - verification of the possibility to trace the person who authorised release of the product; - verification of any instructions for use of the product with relative hazards if improperly or misused.
8.7 Control of nonconforming outputs	
The need to manage nonconformities through appropriate action, based on the nature of the nonconformity and its effect on the conformity of products and services has been clearly defined. The need to inform the customer has also been made clear. The standard requires a guarantee that problems, which could arise during the output, concerning the various stages of the entire production process/provision of the service, be dealt with. Management of nonconformities is closely linked to the type of product/service. Some limitations related to choice of the action to be taken, which the standard gives in points a) to d) are linked, for example, to regulatory references which the products are to strictly meet, to the process stage in which the nonconformity is recognised (nonconformity of the incoming material, nonconformity of the production process, nonconformity of the finished product) and to placing the product or not on the market or the provision or not of the service. In the case of organisations that provide services, the nonconformity is generally found downstream of the provision. An assessment of the potential risks which could occur, in the case of a nonconformity, is useful in order to plan the action to be taken. NB: the organisation is to treat any deficiencies found, relating to semi-finished products or during intermediate stages related to service provision, as nonconformities.	Compliance with the requirement could be assessed through: - verification of the methods of dealing with the nonconformities and related records (for example, practices, instructions, forms); - evidence of the nonconformities found having been dealt with and of the correction made related to each one; - records related to information to the customer; - documentation related to re-verification of the corrected product; - any concessions obtained from authorised persons to place on the market/release/provide the service; - verification of the authority available to the personnel providing the service to decide on time involved and tools (for example, if and when to interrupt the provision of nonconforming output, how to correct/replace the service); - verification of measures implemented in relation to the handling of nonconformities (for example, refunds, new offers, credits ...); - identification, segregation and replacement of any means/equipment.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
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9 Performance evaluation	
9.1 Monitoring, measurement, analysis and evaluation	
9.1.1 General	
The requirement explains the planning of the monitoring activities related to the product/service. The monitoring, measurement and analysis activities serve to guarantee the effectiveness of the quality management system and continuous conformity to the requirements/objectives which the organisation has established. Thus, the organisation shall determine the most appropriate control methods and frequency to carry out these activities and shall ensure that they are performed. Moreover, the organisation shall retain documented information as evidence of the results.	Compliance with the requirement could be checked through: - verification of the criteria determined to perform monitoring and measurement, in line with the results of the assessment of risk/opportunities; - verification of how the monitoring results are managed; - examination of documented information as evidence of the monitoring, controls and measurements performed.
9.1.2 Customer satisfaction	
The organisation shall monitor the degree to which its customers' needs and expectations have been fulfilled. The methods to evaluate customer satisfaction may be direct or indirect. Examples of direct methods are: - telephone surveys or feedback after product/service delivery; - questionnaires to be completed over the phone or in paper format. Examples of indirect methods are: - analysis of offers which have not turned into orders; - analysis of complaints received; - historicity of orders; - market feedback (i.e. returns, credit note requests, repairs during warranty, review of cancellations, order changes).	Compliance with the requirement could be checked through: - verification of how customer satisfaction is monitored, including frequency; - existence of a system to collect, analyse and use customer satisfaction data.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
9.1.3 Analysis and evaluation	
The requirement gives greater emphasis to the importance of the analysis and evaluation of monitoring and measurement data and information to demonstrate planning effectiveness. The standard indicates the aspects which can be evaluated through an analysis of data, also using statistical techniques.	Compliance with the requirement could be checked through: - verification of the planning of data to be collected; - verification of the data collection method; - verification of the data analysis method; - examination of the data analysis results; - analysis of the management review output.
9.2 Internal audit	
The standard, as well as specifying the reasons for conducting internal audits, clarifies methods and requirements to be taken into account when preparing the internal audit programme. Reference is always to be made to the ISO 19011 standard for the conduct of audits. Auditor impartiality and independence in relation to the process being audited are always to be guaranteed.	Compliance with the requirement could be checked through: - verification of an audit programme; - examination of audit reports; - verification of auditor competency and independence; - verification of the actions taken following audit results; - analysis of the management review.
9.3 Management review	
9.3.1 General	
9.3.2 Management review inputs	
9.3.3 Management review outputs	
The standard indicates the aspects to be taken into consideration as input and output of the review; it is to be noted that the input elements have been extended compared to the previous edition of the standard. The management review shall involve the persons with decision-making power, able to intervene and act. The aim is to verify that the quality management system continues to remain adequate and effective, in accordance with the organisation's strategic direction. The review shall be conducted at planned intervals; every organisation, in relation to its structure, can decide the frequency. As well as the input established by the standard, other input can be considered, as for example: - analysis of the data as per point 8.4; - training needs; - problems related to external providers; - need for new equipment and its maintenance; - state of the work environment and infrastructure. The results of the review shall be recorded and should provide evidence of the effectiveness of the review and consistency of its conclusions with the quality policy and objectives.	Compliance with the requirement could be checked through: - verification of review planning and the logic behind the planning (risk analysis); - verification of the existence of documented information which bears witness to the recording of the periodically conducted reviews. The review output should include: - improvement opportunities; - decisions related to the actions to be taken; - assignment of responsibility and adequate resources for each activity; - need to modify the management system; - need for resources.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
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10 Improvement	
10.1 General	
A new requirement has been introduced concerning the approach to improvement in general. Improvement is to be seen as an ongoing activity: each time an opportunity for improvement is identified, the organisation should decide whether to pursue it and the resources needed. Improvement does not just mean product/service improvement but also improvement of the management system. The improvement process can include a series of stages, among which: - identification of potential opportunities to improve the quality management system; - cost/benefit analysis to implement improvement action; - evaluation of resources needed; - decisions related to implementation of an improvement action; - implementation of the improvement action; - measurement of the improvement impact; - assessment of the results at the next management review. -	The quality management system improvement objectives should be in line with the expectations of the organisation and interested parties and with customer and market requirements. The auditor should assess continuous product/service improvement by taking into account, for example, process capability and stability, comparing the characteristics of the product/service with the customer's requirements. It is possible to find evidence related to the improvement process in various areas of the quality management system. Evidence of the action to be taken could be found as: - output of the management review; - consequence of the implementation of a corrective action; - consequence of company reorganisation; - development of new projects/business lines.
To avoid the recurrence of nonconformities (see also point 8.7), corrective action is to be taken related to the management system. Corrective action is an important improvement activity as it aims to permanently eliminate, wherever possible, the causes and effects of undesired events which could have a negative impact on the organisation's results, on provision of the product/service, on the processes, on the management system and on customer satisfaction. Corrective action may be necessary following: - nonconformities; - problems with external providers; - customer complaints; - requests for assistance during warranty; - internal audits (see 9.2). The extent of the problem and related risks for the organisation determine the actions to be taken. The standard illustrates the actions the organisation shall take following a nonconformity. It shall be ensured that the effects of the corrective action taken in one area do not adversely affect other areas of the organisation.	Compliance with the requirement could be checked through: - examination of records related to nonconformity management; - verification that the nonconformities found have been taken into account in the management review; - verification that the effectiveness of the corrective action taken has been evaluated.

DESCRIPTION OF THE REQUIREMENT AND RELATED CONSIDERATIONS	POSSIBLE EVIDENCE TO SUPPORT CONFORMITY
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10.3 Continual improvement	
Emphasis has been given to the outputs of the data analysis and management review. Continual improvement of the management system is an integral part of the objectives established by the Top Management. Improvement should be understood as a continuous sequence of activities which the organisation decides to undertake.	Compliance with the requirement could be checked through: - examination of the output of the management system review; - examination of any improvement strategies and policies; - examination of any improvement programmes (divided into projects, actions, initiatives...) and their continual updating by the organisation.

ANNEX – 1

ISO 9001:2008 to ISO 9001 - Correlation Matrix

<i>ISO 9001:2008</i>	ISO 9001:2015
4 Quality management system	4 Context of the Organization 4.4 Quality management system and its processes
4.1 General requirements	4.4 Quality management system and its processes
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality manual	4.3 Determining the scope of the quality management system 7.5.1 General 4.4 Quality management system and its processes
4.2.3 Control of documents	7.5.2 Creating and updating 7.5.3 Control of documented Information
4.2.4 Control of records	7.5.2 Creating and updating 7.5.3 Control of documented Information
5 Management responsibility	5 Leadership
5.1 Management commitment	5.1 Leadership and commitment
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy
5.4 Planning	6 Planning for the quality management system
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6 Planning for the quality management system
5.5 Responsibility, authority and communication	5 Leadership
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	5.3 Organizational roles, responsibilities and authorities
5.5.3 Internal communication	7.4 Communication
5.6 Management review	9.3 Management review
5.6.1 General	9.3.1 General

ISO 9001:2008	ISO 9001:2015
5.6.2 Review input	9.3.2 Management review inputs
5.6.3 Review output	9.3.3 Management review outputs
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General 7.1.2 People
6.2 Human resources	7.2 Competence
6.2.1 General	7.2 Competence
6.2.2 Competence, training and awareness	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment	7.1.4 Environment for the operation of processes
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Requirements related to products and services
7.2.1 Determination of requirements related to the product	8.2.2 Determination of requirements related to products and services
7.2.2 Review of requirements related to the product	8.2.3 Review of requirements related to the products and services
7.2.3 Customer communication	8.2.1 Customer communication
7.3 Design and development	8.3 Design and development of products and services
7.3.1 Design and development planning	8.3.1 General 8.3.2 Design and development planning
7.3.2 Design and development inputs	8.3.3 Design and development Inputs
7.3.3 Design and development outputs	8.3.5 Design and development outputs
7.3.4 Design and development review	8.3.4 Design and development controls
7.3.5 Design and development verification	8.3.4 Design and development controls
7.3.6 Design and development validation	8.3.4 Design and development controls
7.3.7 Control of design and development changes	8.3.6 Design and development changes
7.4 Purchasing	8.4 Control of externally provided processes, products and services
7.4.1 Purchasing process	8.4.1 General 8.4.2 Type and extent of control

ISO 9001:2008	ISO 9001:2015
7.4.2 Purchasing information	8.4.3 Information for external providers
7.4.3 Verification of purchased product	8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision 8.5.5 Post-delivery activities
7.5.2 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
8.0 Measurement, analysis and improvement	9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal audit	9.2 Internal audit
8.2.3 Monitoring and measurement of processes	9.1.1 General
8.2.4 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 Continual improvement	10.1 General 10.3 Continual Improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	6.1 Actions to address risks and opportunities (see 6.1.1, 6.1.2)

ANNEX – 2

Examples of implementation of requirement 4.1

	Internal issues	External issues
Product/market	Ability to meet customer expectations	Mandatory requirements, competitors, brand recognition, customer expectations
Environmental factors	Management of emissions, waste, availability of adequate space, suitable climatic conditions for the processes	Environmental conditions, availability and cost of raw materials and energy
Economic and political factors	Credit access, cost of labour, funds available for investment, taxation system, investors	Competitors and their commercial policies, customer solvency, payment terms and conditions of external providers, currency exchange risks, political stability of the countries of destination of the products
Human resources	Organisational structure, policies and strategies, decision-making processes, tendency to risk, tendency towards innovation, know-how, ability to communicate internally, with customers, with stakeholders, employee expectations, cultural context in which the organisation operates	Contractual relationship with customers and external providers, relationship with and expectations of interested parties, relationship with the public administration, relationship with regulatory bodies, trade union relations, relations with sectorial associations
Infrastructure	Availability of space, plants, technology and systems	Transport of goods

ANNEX - 3

“RISK” IN ISO 9001:2015

1. Objective of this paper

- to explain how risk is addressed in ISO 9001
- to explain what is meant by ‘opportunity’ in ISO 9001
- to address the concern that risk-based thinking *replaces* the process approach
- to address the concern that preventive action has been removed from ISO 9001
- to explain in simple terms each element of a risk-based approach

2. Overview

One of the key changes in the 2015 revision of ISO 9001 is to establish a systematic approach to risk, rather than treating it as a single component of a quality management system.

In previous editions of ISO 9001, a clause on preventive action was separated from the whole. Now risk is considered and included throughout the standard.

By taking a risk-based approach, an organization becomes proactive rather than purely reactive, preventing or reducing undesired effects and promoting continual improvement. Preventive action is automatic when a management system is risk-based.

3. What is risk-based thinking?

Risk-based thinking is something we all do automatically.

Example: If I wish to cross a road I look for traffic before I begin. I will not step in front of a moving car.

Risk-based thinking has always been in ISO 9001 – this revision builds it into the whole management system.

In ISO 9001:2015 risk is considered from the beginning and throughout the standard, making preventive action part of strategic planning as well as operation and review.

Risk-based thinking is already part of the process approach.

Example: To cross the road I may go directly or I may use a nearby footbridge. Which process I choose will be determined by considering the risks.

Risk is commonly understood to be negative. In risk-based thinking opportunity can also be found – this is sometimes seen as the positive side of risk.

Example:

Crossing the road directly gives me an opportunity to reach the other side quickly, but there is an increased risk of injury from moving cars.

The risk of using a footbridge is that I may be delayed. The opportunity of using a footbridge is that there is less chance of being injured by a car.

Opportunity is not always directly related to risk but it is always related to the objectives. By considering a situation it may be possible to identify opportunities to improve.

Example:

Analysis of this situation shows further opportunities for improvement:

- *a subway leading directly under the road*
- *pedestrian traffic lights, or*
- *diverting the road so that the area has no traffic*

It is necessary to analyse the opportunities and consider which can or should be acted on. Both the impact and the feasibility of taking an opportunity must be considered. Whatever action is taken will change the context and the risks and these must then be reconsidered.

4. Where is risk addressed in ISO 9001:2015?

INTRODUCTION

The concept of risk-based thinking is explained in the introduction of ISO 9001:2015.

DEFINITIONS

ISO 9001:2015 defines risk as *the effect of uncertainty on an expected result*.

1. An effect is a deviation from the expected – positive or negative.
2. Risk is about what *could* happen and what the effect of this happening *might* be
3. Risk also considers how *likely* it is

The target of a management system is achieve conformity and customer satisfaction.

ISO 9001:2015 uses risk-based thinking to achieve this in the following way:

Clause 4 (Context) the organization is required to determine the risks which may affect this.

Clause 5 (Leadership) top management are required to commit to ensuring Clause 4 is followed.

Clause 6 (Planning) the organization is required to take action to identify risks and opportunities.

Clause 8 (Operation) the organization is required to implement processes to address risks and opportunities.

In **Clause 9 (Performance evaluation)** the organization is required to monitor, measure, analyse and evaluate the risks and opportunities.

In **Clause 10 (Improvement)** the organization is required to improve by responding to changes in risk.

5. Why use risk-based thinking?

By considering risk throughout the organization the likelihood of achieving stated objectives is improved, output is more consistent and customers can be confident that they will receive the expected product or service.

Risk-based thinking therefore:

- builds a strong knowledge base
- establishes a proactive culture of improvement
- assures consistency of quality of goods or services
- improves customer confidence and satisfaction

Successful companies intuitively take a risk-based approach

6. How do I do it?

Use a risk-driven approach in your organizational processes.

Identify what YOUR risks and opportunities are – it depends on context

Example

If I cross a busy road with many fast-moving cars the risks are not the same as if the road is small with very few moving cars. It is also necessary to consider such things as weather, visibility, personal mobility and specific personal objectives.

Analyse and prioritize your risks and opportunities

What is acceptable, what is unacceptable? What advantages or disadvantages are there to one process over another?

Example

Objective: I need to safely cross a road to reach a meeting at a given time.

It is UNACCEPTABLE to be injured.

It is UNACCEPTABLE to be late.

The opportunity of reaching my goal more quickly must be balanced against the likelihood of injury. It is more important that I reach my meeting uninjured than it is for me to reach my meeting on time.

It may be ACCEPTABLE to delay arriving at the other side of the road by using a footbridge if the likelihood of being injured by crossing the road directly is high.

I analyse the situation. The footbridge is 200 metres away and will add time to my journey. The weather is good, the visibility is good and I can see that the road does not have many cars at this time.

I decide that walking directly across the road carries an acceptably low level of risk of injury and an opportunity to reach my meeting on time.

Plan actions to address the risks

How can I avoid or eliminate the risk? How can I mitigate risks?

Example: I could eliminate risk of injury by using the footbridge but I have already decided that the risk involved in crossing the road is acceptable.

Now I plan how to reduce the likelihood of injury and/or the effect of injury. I cannot reasonably expect to control the effect of a car hitting me. I can reduce the probability of being hit by a car.

I plan to cross at a time when there are no cars moving near me and so reduce the likelihood of an accident. I also choose to cross the road at a place where I have good visibility and can safely stop in the middle to re-assess the number of moving cars, further reducing the probability of an accident.

Implement the plan – take action

Example

I move to the side of the road, check there are no barriers to crossing and that there is a safe place in the centre of the moving traffic. I check there are no cars coming. I cross half of the road and stop in the central safe place. I assess the situation again and then cross the second part of the road.

Check the effectiveness of the actions – does it work?

Example

I arrive at the other side of the road unharmed and on time: this plan worked and undesired outcomes have been avoided.

Learn from experience – continual improvement

Example

I repeat the plan over several days, at different times and in different weather conditions.

This gives me data to understand that changing context (time, weather, quantity of cars) directly affects the effectiveness of the plan and increases the probability that I will not achieve my objectives (being on time and avoiding injury).

Experience teaches me that crossing the road at certain times of day is very difficult because there are too many cars.

To limit the risk I revise and improve my process by using the footbridge at these times.

I continue to analyse the effectiveness of the processes and revise them when the context changes.

I also continue to consider innovative opportunities:

- *can I move the meeting place so that the road does not have to be crossed?*
- *can I change the time of the meeting so that I cross the road when it is quiet?*
- *can we meet electronically?*

7. Conclusion

- risk-based thinking is not new
- risk-based thinking is something you do already
- risk-based thinking is continuous
- risk-based thinking ensures greater knowledge and preparedness
- risk-based thinking increases the probability of reaching objectives
- risk-based thinking reduces the probability of poor results
- risk-based thinking makes prevention a habit

Useful documents

ISO 31000:2009 Risk Management – Principles and guidelines

PD ISO/TR 31004:2013. Risk management - Guidance for the implementation of ISO 31000

ANNEX - 4

Non-exhaustive examples of possible risks referable to the context/interested parties

Threat	Note
Cybernetic attack	
IT- telephone	
Data loss	
Interruption of external provision	
Destabilisation of external provision chain	
Security theft	
Climatic events (i.e. earthquakes, floods, tsunami, etc.)	In relation to the context
Illness (i.e. disease, infirmity, indisposition, etc.)	
Fire	
Acts of terrorism	In relation to the context
Industrial accidents	In relation to the seriousness
New laws and regulations	
Laws and regulations	
Availability of competency	
Social instability	In relation to the context
Availability of energy / cost	
Product NC	
Environmental incidents	In relation to the context
Ethics / business	In relation to the context
Wars and conflicts	In relation to the context
Industrial controversy	
Defective product liability	
Insolvency of main customers	
Cost / financing availability	In relation to the orders acquired
Volatility of money exchange rates	In relation to the orders acquired
Scarcity of natural resources	
Closure of airspace	In relation to the orders

	acquired
Animal diseases /epidemics	In relation to the context

ANNEX - 5

Considerations on how to conduct audits for conformity to ISO 9001:2015

The method for conducting audits is essentially unchanged.

In order to have reasonable certainty of system conformity to the requirements, an auditor should however modify his/her approach from “search for conformity” to greater “conformity assessment” of the management system.

An example can be given by checking the adequacy of the documented information, which an organisation has the right to determine to ensure effective implementation of the quality management system. Examination of this documented information should contribute to the auditor’s assessment of the effectiveness of the system.

In view of the top management’s greater and explicit involvement required, it would be advisable for auditors to request top management participation at the opening and closing meetings, in particular, but also during the audit process.

During this meeting, which takes on considerable importance as concerns quality management system assessment, the top management should be asked to illustrate how the context in which the organisation operates has been identified and how a “Risk Based Approach” has been taken into account in the planning of the quality management system and should be able to justify all decisions taken to plan and manage the company system. It shall also demonstrate how it pursues its policy, which instruments and means it uses and how it ensures implementation by the personnel. The management’s effectiveness in this sense can be evaluated throughout the audit by means of interviews or talks with the personnel and by verifying the outputs of the various processes.

An open-ended question approach should be adopted to allow interviewees to explain how system implementation is ensured and to allow the auditor to assess their replies.

A result-based approach (Bottom Up) is also to be preferred. If the result is a nonconformity, this means there is a “hole” in the management system. The organisation is to be called upon to analyse the causes and propose real corrective action. Also “mystery audit” methods may be adopted for organisations which provide services.

POSSIBLE CRITICAL POINTS FOR THE ORGANISATION

- Context
- Quality system expectations
- Identification of risks and opportunities
- Identification of interested parties
- Identification of roles and responsibilities
- Identification of competences
- Documented information (Expectations)

POSSIBLE CRITICAL ASPECTS FOR AUDITORS

- Management system scope
- Knowledge of the context in which the organisation operates
- Top management responsibility
- Adequacy of the documented information

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Associazione Organismi Certificazione Ispezione Prove Taratura

Piazzale R. Morandi, 2, 20121 Milano – telefono 02.77790408 - 02.77790409

info@associazioneconforma.eu – www.associazioneconforma.eu

c.f. p.iva 07671900962