

DNV GL
Assessment Checklist
ISO 9001:2015

4 Context of the Organization

No.	Question	Proc. Ref.	Comments
	4.1 Understanding the Organization and its context		
1	Has the organization determined external and internal issues that are relevant to its purpose, strategic direction and that affect its ability to achieve the intended result(s) of its quality management system?		
2	Is the organization monitoring and reviewing information about these external and internal issues?		
	4.2 Understanding the needs and expectations of interested parties		
3	Has the organization:		
	a) Determined the interested parties that are relevant to the quality management system?		
	b) Determined the requirements of these interested parties that are relevant to the quality management system?		
4	Is the organization reviewing and monitoring information about these interested parties and their relevant requirements?		
	4.3 Determining the scope of the quality management system		
5	Has the organization determined the boundaries and the applicability of the quality management system in order to establish its scope?		
6	When establishing the scope has the organization taken into consideration:		
	a) The external and internal issues referred to in <u>4.1</u> ?		
	b) The requirements of relevant interested parties referred to in <u>4.2</u> ?		
	c) The products and services of the organization?		
7	Has the organization applied all of the requirements of the ISO 9001:2015 International Standard (if applicable) within the determined scope of its quality management system?		
8	Is the scope of the organization's quality management system available and maintained as documented information?		
9	Does the organization's scope state the types of products and services covered?		

10	Does the scope provide any justification for any requirement of the ISO 9001:2015 International Standard that the organization determines is not applicable to the scope of its quality management system?		
11	Can the organization claim conformity to the ISO 9001:2015 International Standard by:		
	a) Ensuring that requirements determined as not applicable do not affect the organization's ability or responsibility to ensure the conformity of its products, services and enhancement of customer satisfaction?		
	4.4 Quality Management System and its Processes		
	4.4.1		
12	Has the organization established, implemented, maintained and continually improved the quality management system including the processes needed and their interactions?		
13	Has the organization determined the processes needed for the quality management system and their application throughout the organization by:		
	a) Determining the inputs required and the outputs expected from these processes?		
	b) Determining the sequence and interaction of these processes?		
	c) Determining and applying the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes?		
	d) Determining the resources needed for these processes and ensuring their availability?		
	e) Assigning responsibility and authority for these processes?		
	f) Addressing the risks and opportunities as determined in accordance with the requirements of <u>6.1</u> ?		
	g) Evaluating these processes and implementing any changes needed to ensure that these processes achieve their intended results?		
	h) Improving the processes and the quality management system?		
	4.4.2		
14	Has the organization to the extent necessary:		

	a) Maintained documented information to support the operation of its processes?		
	b) Retained documented information to have confidence that the processes are being carried out as planned?		

5 Leadership

No.	Question	Proc. Ref.	Comments
	5.1 Leadership and commitment		
	<i>5.1.1 General</i>		
1	Has top management demonstrated leadership and commitment with respect to the quality management system by:		
	a) Taking accountability for the effectiveness of the quality management system?		
	b) Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization?		
	c) Ensuring the integration of the quality management system requirements into the organization's business processes?		
	d) Promoting the use of the process approach and risk-based thinking?		
	e) Ensuring that the resources needed for the quality system are available?		
	f) Communicating the importance of effective quality management and of conforming to the quality management system requirements?		
	g) Ensuring that the quality management system achieves its intended results?		
	h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system?		
	i) Promoting improvement?		
	j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility?		
	<i>5.1.2 Customer Focus</i>		
2	Has top management demonstrated leadership and commitment with respect to customer focus by:		
	a) Ensuring that customer and applicable statutory and regulatory requirements are		

	determined, understood and consistently met?		
	b) Ensuring that the risks and opportunities that can affect conformity of products and services along with the ability to enhance customer satisfaction are determined and addressed?		
	c) Ensuring that the focus on enhancing customer satisfaction is maintained?		
	5.2 Policy		
	<i>5.2.1 Establishing the quality policy</i>		
3	Has top management established, implemented and maintained a quality policy that:		
	a) Is appropriate to the purpose and context of the organization and supports its strategic direction?		
	b) Can provide a framework for setting quality objectives?		
	c) Includes a commitment to continual improvement to satisfy applicable requirements?		
	d) Includes a commitment to continual improvement of the quality management system?		
	<i>5.2.2 Communicating the Quality Policy</i>		
4	Is the quality policy:		
	a) Available and maintained as documented information?		
	b) Communicated, understood and applied within the organization?		
	c) Available to relevant interested parties, as appropriate?		
	5.3 Organizational roles, responsibilities and authorities		
5	Has top management ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization?		
6	Has top management assigned the responsibility and authority by:		
	a) Ensuring that the quality management system conforms to the requirements of the ISO 9001:2015 International Standard?		
	b) Ensuring that the processes are delivering their intended outputs?		
	c) Reporting on the performance of the quality management system and on		

	opportunities for improvement (see 10.1) in particular to top management?		
	d) Ensuring the promotion of customer focus throughout the organization?		
	e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented?		

6 Planning

No.	Question	Proc. Ref.	Comments
	6.1 Actions to address risks and opportunities		
	6.1.1		
1	Has the organization considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed?		
2	Has the organization:		
	a) Given assurance that the quality management system can achieve its intended results?		
	b) Enhanced desirable effects?		
	c) Prevented or reduced undesired effects?		
	d) Achieved improvement?		
	6.1.2		
3	Has the organization planned:		
	a) Actions to address these risks and opportunities?		
	b) How to integrate and implement the actions into its quality management system processes (see 4.4) and evaluate the effectiveness of these actions?		
4	Has the organization taken actions to address risks and opportunities that are proportionate to the potential impact on the conformity of products and services?		
	6.2 Quality objectives and planning to achieve them		
	6.2.1		
5	Has the organization established quality objectives at relevant functions, levels and		

	processes needed for the quality management system?		
6	Has the organization developed quality objectives that:		
	a) Are consistent with the quality policy?		
	b) Are Measurable?		
	c) Take into account applicable requirements?		
	d) Are relevant to conformity of products and services and to enhancement of customer satisfaction?		
	e) Are monitored?		
	f) Are communicated?		
	g) Are updated as appropriate?		
7	Has the organization maintained documented information on the quality objectives?		
	6.2.2		
8	When planning how to achieve quality objectives has the organization determined:		
	a) What will be done?		
	b) What resources will be required?		
	c) Who will be responsible?		
	d) When it will be completed?		
	e) How the results will be evaluated?		
	6.3 Planning of changes		
9	Has the organization determined the need for changes to the quality management system and carried those changes out in a planned manner (see 4.4)?		
10	When planning for changes has the organization considered:		
	a) The purpose of the changes and their potential consequences?		
	b) The integrity of the quality management system?		
	c) The availability of resources?		
	d) The allocation or reallocation of responsibilities and authorities?		

7 Support

No.	Question	Proc. Ref.	Comments
	7.1 Resources		
	<i>7.1.1 General</i>		
1	Has the organization determined and provided the resources necessary for the establishment, implementation, maintenance and continual improvement of the quality management system?		
2	When providing resources has the organization considered:		
	a) The capabilities of, and constraints on, existing internal resources?		
	b) What needs to be obtained from external providers?		
	<i>7.1.2 People</i>		
3	Has the organization determined and provided the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes?		
	<i>7.1.3 Infrastructure</i>		
4	Has the organization determined, provided and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services?		
	<i>7.1.4 Environment for the operation of processes</i>		
5	Has the organization determined, provided, and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services?		
	<i>7.1.5 Monitoring and measuring resources</i>		
	<i>7.1.5.1 General</i>		
6	Has the organization determined and provided the resources needed to ensure valid and reliable results when monitoring and measuring is used to verify the conformity of products and services to requirements?		
7	Has the organization ensured that the resources provided:		
	a) Are suitable for the specific type of monitoring and measurement activities being undertaken?		
	b) Are maintained to ensure their continuing fitness for their purpose?		

8	Has the organization retained documented information as evidence of fitness for purpose of the monitoring and measurement resources?		
	<i>7.1.5.2 Measurement Traceability</i>		
9	Has the organization ensured that when measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, that measuring equipment is:		
	a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards and when no such standards exist, the basis used for calibration or verification is retained as documented information?		
	b) Identified in order to determine their status?		
	c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?		
10	Has the organization determined if the validity of previous measurement results have been adversely affected when measuring equipment is found to be unfit for its intended purpose, and takes appropriate action as necessary?		
	<i>7.1.6 Organizational knowledge</i>		
11	Has the organization determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services?		
12	Has this knowledge been maintained and made available to the extent necessary?		
13	Has the organization when addressing its changing needs and trends, considered its current knowledge and determined how to acquire or access any necessary additional knowledge and required updates?		
	7.2 Competence		
14	Has the organization:		
	a) Determined the necessary competence of a person(s) doing work under its control that affects the performance and effectiveness of the quality management system?		
	b) Ensured that these persons are competent on the basis of appropriate education,		

	training, or experience?		
	c) Ensured where applicable taken actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken?		
	d) Retained appropriate documented information as evidence of competence?		
	7.3 Awareness		
15	Has the organization ensured that the persons doing work under the organization's control are aware of:		
	a) The quality policy?		
	b) Relevant quality objectives?		
	c) Their contribution to the effectiveness of the quality management system, including benefits of improved performance?		
	d) The implications of not conforming with the quality management system requirements?		
	7.4 Communication		
16	Has the organization determined the internal and external communications relevant to the quality management system including:		
	a) What it will communicate?		
	b) When to communicate?		
	c) With whom to communicate?		
	d) How to communicate?		
	e) Who communicates?		
	7.5 Documented Information		
	<i>7.5.1 General</i>		
17	Has the organization's quality management system included documented information that:		
	a) Is required by the ISO 9001:2015 International Standard?		
	b) Is documented information determined by the organization as being necessary for the effectiveness of the quality management system?		
	<i>7.5.2 Creating and updating</i>		
18	When creating and updating documented information has the organization ensured:		

	a) The documented information has an appropriate identification and description?		
	b) The documented information has an appropriate format?		
	c) The documented information has been reviewed and approved for suitability and adequacy?		
	<i>7.5.3 Control of documented information</i>		
	<i>7.5.3.1</i>		
19	Has the organization ensured that documented information required by the quality management system and by the ISO 9001:2015 standard is controlled to ensure:		
	a) That is available and suitable for use, where and when it is needed?		
	b) That it is adequately protected (from loss of confidentiality, improper use, or loss of integrity)?		
	<i>7.5.3.2</i>		
20	Has the organization, in order to control documented information, addressed:		
	a) Its distribution, access, retrieval and use?		
	b) Its storage and preservation, including preservation of legibility?		
	c) Its control of changes (e.g. version control)?		
	d) Its retention and disposition?		
21	Has the organization determined documented information of external origin necessary for the planning and operation of the quality management system be identified as appropriate, and be controlled?		
22	Has the organization retained documented information as evidence of conformity and protected it from unintended alterations?		

8 Operation

No.	Question	Proc. Ref.	Comments
	8.1 Operational planning and control		
1	Has the organization planned, implemented and controlled the processes (see 4.4) needed to meet the requirements for the provision of		

	products and services and implemented the actions determined in <u>Clause 6</u> , by:		
	a) Determining the requirements for the products and services?		
	b) Establishing criteria for the processes and the acceptance of products and services?		
	c) Determining the resources needed to achieve conformity to the product and service requirements?		
	d) Implementing control of the processes in accordance with the criteria?		
	e) Determining, maintaining and retaining documented information to the extent necessary to ensure:		
	1. Processes have been carried out as planned?		
	2. That conformity of products and services have been demonstrated to their requirements?		
2	Has the organization ensured that the output of this planning is suitable for the organization's operations?		
3	Has the organization controlled planned changes and reviewed the consequences of unintended changes while taking action to mitigate any adverse effects?		
4	Has the organization ensured that outsourced processes are controlled?		
	8.2 Requirements for products and services		
	<i>8.2.1 Customer communication</i>		
5	Has the organization ensured that communication with customers includes:		
	a) Providing information relating to products and services?		
	b) Handling enquiries, contracts or orders, including changes?		
	c) Obtaining customer feedback relating to products and services, including customer complaints?		
	d) Handling or controlling customer property?		
	e) Establishing specific requirements for contingency actions, when relevant?		
	<i>8.2.2 Determining the requirements for products and services</i>		
6	Has the organization when determining the requirements for products and services offered to		

	customers ensured that:		
	a) The requirements for the products and services are defined including: applicable statutory and regulatory requirements along with those considered necessary by the organization?		
	b) The organization can meet the claims for the products and services it offers?		
	<i>8.2.3 Review of the requirements for products and services</i>		
	8.2.3.1		
7	Has the organization ensured that it has the ability to meet the requirements for products and services to be offered to customers?		
8	Has the organization conducted a review before committing to supply products and services to a customer that includes:		
	a) Requirements specified by the customer, including requirements for delivery and post-delivery activities?		
	b) Requirements not stated by the customer, but necessary for the specified or intended use, when known?		
	c) Requirements specified by the organization?		
	d) Statutory and regulatory requirements applicable to the products and services?		
	e) Contract or order requirements differing from those previously expressed?		
9	Has the organization ensured that contract or order requirements differing from those previously defined are resolved?		
10	Has the organization ensured that customer requirements are confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements?		
	<i>8.2.3.2</i>		
11	Has the organization retained documented information as applicable:		
	a) On the results of the review?		
	b) On any new requirements for the products and services?		
	<i>8.2.4 Changes to requirements for products and services</i>		
12	Has the organization ensured that relevant documented information is amended, and that relevant persons are made aware of the changed		

	requirements, when the requirements for products and services are changed?		
	8.3 Design and development of products and services		
	<i>8.3.1 General</i>		
13	Has the organization established, implemented and maintained a design and development process that is appropriate to ensure the subsequent provision of products and services?		
	<i>8.3.2 Design and development planning</i>		
14	Has the organization in determining the stages and controls for design and development, considered:		
	a) The nature, duration and complexity of the design and development activities?		
	b) The required process stages, including applicable design and development reviews?		
	c) The required design and development verification and validation activities?		
	d) The responsibilities and authorities involved in design and development process?		
	e) The internal and external resource needs for the design and development of products and services?		
	f) The need to control interfaces between persons involved in the design and development process?		
	g) The need for involvement of customers and users in the design and development process?		
	h) The requirements for subsequent provision of products and services?		
	i) The level of control expected for the design and development process by customers and other relevant interested parties?		
	j) The documented information needed to demonstrate that the design and development requirements have been met?		
	<i>8.3.3 Design and development inputs</i>		
15	Has the organization determined the requirements essential for the specific types of products and services to be designed and developed by considering:		
	a) Functional and Performance requirements?		

	b) Information derived from previous similar design and development activities?		
	c) Statutory and regulatory requirements?		
	d) Standards or codes of practice that the organization has committed to implement?		
	e) The potential consequences of failure due to the nature of the products and services?		
16	Has the organization ensured that inputs are adequate for design and development purposes, complete and unambiguous?		
17	Has the organization resolved conflicting design and development inputs?		
18	Has the organization retained documented information on design and development inputs?		
	<i>8.3.4 Design and development controls</i>		
19	Has the organization applied controls to the design and development process to ensure that:		
	a) The results to be achieved are defined?		
	b) The reviews are conducted to evaluate the ability of the results of design and development to meet requirements?		
	c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements?		
	d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use?		
	e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities?		
	f) Documented information of these activities is retained?		
	<i>8.3.5 Design and development outputs</i>		
20	Has the organization ensured that design and development outputs:		
	a) Meet the input requirements?		
	b) Are adequate for the subsequent processes for the provision of products and services?		
	c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria?		
	d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision?		

21	Has the organization retained documented information on design and development outputs?		
	<i>8.3.6 Design and development changes</i>		
22	Has the organization identified, reviewed, and controlled changes made during, or subsequently to the design and development of products and services, to ensure that there is no adverse impact on conformity to requirements?		
23	Has the organization retained documented information on:		
	a) The design and development changes?		
	b) The results of reviews?		
	c) The authorization of the changes?		
	d) The actions taken to prevent adverse impacts?		
	8.4 Control of externally provided processes, products and services		
	<i>8.4.1 General</i>		
24	Has the organization ensured that the externally provided processes, products and services conform to requirements?		
25	Has the organization determined the controls to be applied to externally provided processes, products and services when:		
	a) The products and services from external providers are intended for incorporation into the organization's own products and services?		
	b) The products and services are provided directly to the customer(s) by external providers on behalf of the organization?		
	c) A process, or part of a process, is provided by an external provider as a result of a decision by the organization?		
26	Has the organization determined and applied the criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements?		
27	Has the organization retained documented information of these activities and any necessary actions arising from the evaluations?		
	<i>8.4.2 Type and extent of control</i>		
28	Has the organization ensured that externally provided processes, products and services do not adversely affect the organization's ability to		

	consistently deliver conforming products and services to its customers?		
29	Has the organization:		
	a) Ensured that externally provided processes remain within the control of its quality management system?		
	b) Ensured that it has defined both the controls it intends to apply to an external provider and those it intends to apply to the resulting output?		
	c) Taken into consideration the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer requirements along with applicable statutory and regulatory requirements?		
	d) Taken into consideration the effectiveness of the controls applied by the external provider?		
	e) Determined the verification, or other activities, necessary to ensure that externally provided processes, products and services meet requirements?		
	<i>8.4.3 Information for external providers</i>		
30	Has the organization ensured the adequacy of requirements prior to their communication to the external provider?		
31	Has the organization communicated to external providers its requirements for:		
	a) The processes, products and services to be provided?		
	b) The approval of products and services, methods, processes, equipment and the release of products and services?		
	c) Competence, including any required qualification of persons?		
	d) The external provider's interactions with the organization?		
	e) The controlling and monitoring of external providers' performance applied by the organization?		
	f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises?		
	8.5 Production and service provision		
	<i>8.5.1 Control of production and service provision</i>		

32	Has the organization implemented production and service provision under controlled conditions that includes:		
	a) The availability of documented information that defines the characteristics of the products to be produced, services to be provided, or the activities to be performed and the results to be achieved?		
	b) The availability and use of suitable monitoring and measuring resources?		
	c) The implementation of monitoring and measurement activities at appropriate stages to verify the criteria for control of processes or outputs and that acceptance criteria for products and services have been met?		
	d) The use of suitable infrastructure and environment for the operation of processes?		
	e) The appointment of competent persons, including any required qualification?		
	f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision when the resulting output cannot be verified by subsequent monitoring or measurement?		
	g) The implementation of actions to prevent human error?		
	h) The implementation of release, delivery and post-delivery activities?		
	<i>8.5.2 Identification and traceability</i>		
33	Has the organization used suitable means to identify outputs when it is necessary to ensure the conformity of products and services?		
34	Has the organization identified the status of outputs with respect to monitoring and measuring requirements throughout production and service provision?		
35	Has the organization controlled the unique identification of the outputs when traceability is a requirement and retained the documented information necessary to enable traceability?		
	<i>8.5.3 Property belonging to customers or external providers</i>		
36	Has the organization exercised care with property belonging to customers or external providers while it is under the organization's control or being used by the organization?		

37	Has the organization identified, verified, protected and safeguarded customer or external providers' property provided for use or incorporation into the products and services?		
38	When property of a customer or external provider is lost, damaged or found to be unsuitable for use, has the organization reported this to the customer or external provider and retained documented information on what has occurred?		
	<i>8.5.4 Preservation</i>		
39	Has the organization preserved the outputs during production and service provision, to the extent necessary to ensure conformity to requirements?		
	<i>8.5.5 Post-delivery activities</i>		
40	Has the organization met the requirements for post-delivery activities associated with the products and services?		
41	In determining the extent of the post-delivery activities that are required has the organization considered:		
	a) Statutory and Regulatory requirements?		
	b) The potential undesired consequences associated with its products and services?		
	c) The nature, use and intended lifetime of its products and services?		
	d) Customer requirements?		
	e) Customer feedback?		
	<i>8.5.6 Control of changes</i>		
42	Has the organization reviewed and controlled changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements?		
43	Has the organization retained documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review?		
	8.6 Release of products and services		
44	Has the organization implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?		
45	Has the organization ensured that the release of products and services to the customer not proceed until the planned arrangements have been satisfactorily completed, unless otherwise		

	approved by a relevant authority and as applicable, by the customer?		
46	Has the organization retained documented information on the release of products and services which includes:		
	a) Evidence of conformity with the acceptance criteria?		
	b) Traceability to the person(s) authorizing the release?		
	8.7 Control of nonconforming outputs		
	<i>8.7.1</i>		
47	Has the organization ensured that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery?		
48	Has the organization taken appropriate action on outputs based on the nature of the nonconformity and its effect on the conformity of products and services?		
49	Has the organization also applied action on nonconforming products and services detected after the delivery of products and during or after the provision of services?		
50	Has the organization dealt with nonconforming outputs in one or more of the following ways by:		
	a) Correction?		
	b) Segregation, containment, return or suspension or provision of products and services?		
	c) Informing the customer?		
	d) Obtaining authorization for acceptance under concession?		
51	Has the organization verified conformity to the requirements when nonconforming outputs are corrected?		
	<i>8.7.2</i>		
52	Has the organization retained documented information that:		
	a) Describes the nonconformity?		
	b) Describes the actions taken?		
	c) Describes any concessions obtained?		
	d) Identifies the authority deciding the action in respect of the nonconformity?		

9 Performance Evaluation

No.	Question	Proc. Ref.	Comments
	9.1 Monitoring, measurement, analysis and evaluation		
	<i>9.1.1 General</i>		
1	Has the organization determined:		
	a) What needs to be monitored and measured?		
	b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results?		
	c) When the monitoring and measuring shall be performed?		
	d) When the results from monitoring and measurement are analyzed and evaluated?		
2	Is the organization evaluating the performance and the effectiveness of the quality management system?		
3	Has the organization retained appropriate documented information as evidence of the results?		
	<i>9.1.2 Customer satisfaction</i>		
4	Is the organization monitoring customers' perceptions of the degree to which their needs and expectations are being fulfilled and determining the methods for obtaining, monitoring and reviewing this information?		
	<i>9.1.3 Analysis and evaluation</i>		
5	Is the organization analyzing and evaluating appropriate data and information arising from monitoring and measurement?		
6	Has the organization used the results of the analysis to evaluate:		
	a) The conformity of products and services?		
	b) The degree of customer satisfaction?		
	c) The performance and effectiveness of the quality management system?		
	d) If planning has been implemented effectively?		
	e) The effectiveness of actions taken to address risks and opportunities?		

	f) The performance of external providers?		
	g) The need for improvements to the quality management system?		
	9.2 Internal audit		
	9.2.1		
7	Is the organization conducting internal audits at planned intervals to provide information on whether the quality management system:		
	a) Conforms to the organization's own requirements for its quality management system and the requirements of the ISO 9001:2015 International Standard?		
	b) Is effectively implemented and maintained?		
	9.2.2		
8	Has the organization:		
	a) Planned, established, implemented and maintained an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting which takes into consideration the importance of processes concerned, changes affecting the organization, and the results of previous audits?		
	b) Defined the audit criteria and scope for each audit?		
	c) Selected auditors and conducted audits to ensure objectivity and impartiality of the audit process?		
	d) Ensured that the results of audits are reported to relevant management?		
	e) Taken appropriate correction and corrective actions without undue delay?		
	f) Retained documented information as evidence of the implementation of the audit programme and the audit results?		
	9.3 Management Review		
	9.3.1 <i>General</i>		
9	Has top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing stability, adequacy, effectiveness and alignment with the strategic direction of the organization?		
	9.3.2 <i>Management review inputs</i>		

10	Has the organization planned and carried out taking into consideration:		
	a) The status of actions from previous management reviews?		
	b) Changes in external and internal issues that are relevant to the quality management system?		
	c) Information on the performance and effectiveness of the quality management system which includes trends in:		
	1. Customer satisfaction and feedback from relevant interested parties?		
	2. The extent to which quality objectives have been met?		
	3. Process performance and conformity of products and services?		
	4. Nonconformities and corrective actions?		
	5. Monitoring and measuring results?		
	6. Audit results?		
	7. The performance of external providers?		
	d) The adequacy of resources?		
	e) The effectiveness of actions taken to address risks and opportunities (see 6.1)?		
	f) Opportunities for improvement?		
	<i>9.3.3 Management review outputs</i>		
11	Has the organization ensured that the outputs of the management review includes decisions and actions related to:		
	a) Opportunities for improvement?		
	b) Any need for changes to the quality management system?		
	c) Resource needs?		
12	Is the organization retaining documented information as evidence of the results of the management reviews?		

10 Improvement

No.	Question	Proc. Ref.	Comments
	10.1 General		
1	Has the organization determined and selected opportunities for improvement and implemented any necessary actions to meet customer requirements and enhance customer satisfaction?		
2	Do these opportunities for improvement and necessary actions include:		
	a) Improving products and services to meet requirements as well as to address future needs and expectations?		
	b) Correcting, preventing or reducing undesired effects?		
	c) Improving the performance and effectiveness of the quality management system?		
	10.2 Nonconformity and corrective action		
	<i>10.2.1</i>		
3	When a nonconformity occurs, including any arising from complaints has the organization:		
	a) Reacted to the nonconformity as applicable and taken action to control and correct it and also deal with the consequences?		
	b) Evaluated the need for action to eliminated the cause(s) of the nonconformity, to ensure that it does not recur or occur elsewhere by:		
	1. Reviewing and analyzing the nonconformity?		
	2. Determining the causes of the nonconformity?		
	3. Determining if similar nonconformities exist, or could potentially occur?		
	c) Implemented any action needed?		
	d) Reviewed the effectiveness of any corrective action taken?		
	e) Updated risks and opportunities determined during planning, if necessary?		

	f) Made changes to the quality management system, if necessary?		
4	Has the organization ensured that corrective actions are appropriate to the effects of the nonconformities encountered?		
	10.2.2		
5	Has the organization retained documented information as evidence of:		
	a) The nature of the nonconformities and any subsequent actions taken?		
	b) The results of any corrective action?		
	10.3 Continual improvement		
6	Is the organization continually improving the suitability, adequacy and effectiveness of the quality management system?		
7	Has the organization considered the results of analysis and evaluation, and the outputs from management review to determine if there are needs and opportunities to address as a part of continual improvement?		