

# SELF ASSESSMENT QUESTIONNAIRE

(according to ISO 9001:2015)

Organization:

Date:

## Key:

0 - not implemented

1 - implemented with major(great) inconformity

2 - implemented with minor(less) inconformity

3 - implemented

4 - implemented and has an opportunity to be improved

5 - implemented with continuous improvement

ISO 9001:2015 standard criteria	Questions	Value
<b>1 Context of the organization</b>		<b>0,0</b>
<b>1.1 Understanding the organization and its context</b>	Has the organization determined the external and internal issues that are relevant to organization purpose and its strategic direction and those that affect your ability to achieve the intended results of the quality management system?	
<b>1.1 Understanding the organization and its context</b>	Does the organization monitor and review information about these external and internal issues?	
<b>1.2 Understanding the needs and expectations of interested parties</b>	Has the organization determined the needs and expectations of interested parties that are relevant to the quality management system and review these on a regular basis?	
<b>1.3 Determining the scope of the quality management system</b>	Does the organization determine the boundaries and applicability of the quality management system to establish its scope?	
<b>1.3 Determining the scope of the quality management system</b>	Does the scope of the organization's quality management system available and maintain as documented information?	
<b>1.3 Determining the scope of the quality management system</b>	Has the scope state the types of products and services covered, and provide justification for any requirement of this International Standard that you determines is not applicable to the scope of its quality management system?	
<b>1.4 Quality management system and its processes</b>	Has the organization quality management system been established including the processes needed and their sequence and interaction? Has the organization:	
	a) determined the inputs required and the outputs expected from these processes?	
	b) determined the sequence and interaction of these processes?	
	c) determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective	

	operation and control of these processes?	
	d) determined the resources needed for these processes and ensure their availability?	
	e) assigned the responsibilities and authorities for these processes?	
	f) addressed the risks and opportunities as determined in accordance with the requirements of 6.1?	
	g) evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results?	
	h) improved the processes and the quality management system?	
<b>1.4 Quality management system and its processes</b>	Has the organization:	
	a) maintained documented information to support the operation of yours processes?	
	b) retained documented information to have confidence that the processes are being carried out as planned?	
<b>2 Leadership</b>		
<b>2.1 Leadership and commitment;</b> <b>2.1.1 General</b>	Has top management:	
	a) taken accountability for the effectiveness of the quality management system?	
	b) ensured 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) ensured the integration of the quality management system requirements into the organization's business processes?	
	d) promoted the use of the process approach and risk-based thinking?	
	e) ensured that the resources needed for the quality management system are available?	
	f) communicated the importance of effective quality management and of conforming to the quality management system requirements?	
	g) ensured that the quality management system achieves its intended results?	
	h) engaged, directing and supporting persons to contribute to the effectiveness of the quality management system?	
	i) promoted improvement?	
	j) supported other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility?	
<b>2.1.2 Customer focus</b>	Has top management demonstrate leadership and commitment with respect to customer focus by ensured	

	that:	
	a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met?	
	b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed?	
	c) the focus on enhancing customer satisfaction is maintained?	
<b>2.2 Policy;</b>	Has top management established, implemented and maintained a quality policy that:	
<b>2.2.1 Establishing the quality policy</b>		
	a) is appropriate to the purpose and context of the organization and supports its strategic direction?	
	b) provides a framework for setting quality objectives?	
	c) includes a commitment to satisfy applicable requirements?	
	d) includes a commitment to continual improvement of the quality management system?	
<b>2.2.2 Communicating the quality policy</b>	Has the quality policy:	
	a) been available and been maintained as documented information?	
	b) been communicated, understood and applied within the organization?	
	c) been available to relevant interested parties, as appropriate?	
<b>2.3 Organizational roles, responsibilities and authorities</b>	Has the top management assigned, communicated and understood within the organization the responsibilities and authorities for relevant roles?	
<b>2.3 Organizational roles, responsibilities and authorities</b>	Has the top management assign the responsibility and authority for:	
	a) ensuring that the quality management system conforms to the requirements of this 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?	
<b>3 Planning</b>		
<b>3.1 Quality objectives and</b>	Has the organization established quality objectives at	

<b>planning to achieve them</b>	relevant functions, levels and processes needed for the quality management system?	
<b>3.1 Quality objectives and planning to achieve them</b>	Has the quality objectives:	
	a) been consistent with the quality policy?	
	b) been measurable?	
	c) taken into account applicable requirements?	
	d) been relevant to conformity of products and services and to enhancement of customer satisfaction?	
	e) been monitored?	
	f) been communicated?	
	g) been updated as appropriate?	
<b>3.1 Quality objectives and planning to achieve them</b>	Has the organization documented information on the quality objectives been maintained?	
<b>3.1 Quality objectives and planning to achieve them</b>	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?	
<b>3.2 Planning of changes</b>	When the organization determines the need for changes to the quality management system, has the changes carried out in a planned manner?	
<b>4 Support</b>		
<b>4.1 Resources; 4.1.1 General</b>	Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system?	
<b>4.1.1 General</b>	Has the organization considered:	
	a) the capabilities of, and constraints on, existing internal resources?	
	b) what needs to be obtained from external providers?	
<b>4.1.2 People</b>	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?	
<b>4.1.3 Infrastructure</b>	Has the organization determined, provided and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services?	
<b>4.1.4 Environment for the operation of processes</b>	Has the organization determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services?	
<b>4.1.5 Monitoring and measuring resources</b>	Has the organization determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the	

	conformity of products and services to requirements?	
<b>4.1.5 Monitoring and measuring resources</b>	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?	
<b>4.1.5 Monitoring and measuring resources</b>	Has the organization determined if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and taken appropriate action as necessary?	
<b>4.1.6 Organizational knowledge</b>	Has the organization determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services?	
<b>4.2 Competence</b>	Has the organization:	
	a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system?	
	b) ensure that these persons are competent on the basis of appropriate education, training, or experience?	
	c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken?	
	d) retain appropriate documented information as evidence of competence?	
<b>4.3 Awareness</b>	Has the organization ensured that 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 the benefits of improved performance?	
<b>4.4 Communication</b>	Has the organization determined the internal and external Communications relevant to the quality management system, include:	
	a) on what it will communicate?	
	b) when to communicate?	
	c) with whom to communicate?	
	d) how to communicate?	
	e) who communicates?	
<b>4.5 Documented information;</b> <b>4.5.1 General</b>	Has the organization's quality management system include:	
	a) documented information required by this International Standard?	
	b) documented information determined by the	

	organization as being necessary for the effectiveness of the quality management system?	
<b>5 Performance evaluation</b>		
<b>5.1 Monitoring, measurement, analysis and evaluation; 9.1.1 General</b>	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 shall be analysed and evaluated?	
<b>5.1.1 General</b>	Does the organization evaluate the performance and the effectiveness of the quality management system?	
<b>5.1.1 General</b>	Has the organization retained appropriate documented information as evidence of the results?	
<b>5.1.2 Customer satisfaction</b>	Does the organization monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled? Does the organization determine the methods for obtaining, monitoring and reviewing this information?	
<b>5.1.3 Analysis and evaluation</b>	Does the organization analyse and evaluate appropriate data and information arising from monitoring and measurement?	
<b>5.1.3 Analysis and evaluation</b>	Has the results of analysis been used to evaluate:	
	a) 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?	
<b>5.2 Internal audit</b>	Does the organization conduct internal audits at planned intervals to provide information on whether the quality management system:	
	a) conforms to:	
	1) the organization's own requirements for its quality management system?	
	2) the requirements of this International Standard?	
	b) is effectively implemented and maintained?	
<b>5.3 Management review; 9.3.1 General</b>	Does top management review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the	

	organization?	
<b>5.3.2 Management review inputs</b>	Does the management review be 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, including 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 measurement 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	
	f) opportunities for improvement?	
<b>5.3.3 Management review outputs</b>	Does the outputs of the management review include decisions and actions related to:	
	a) opportunities for improvement?	
	b) any need for changes to the quality management system?	
<b>6 Improvement</b>		
<b>6.1 General</b>	Has the organization determined and selected opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction?	
<b>6.1 General</b>	Has these included:	
	a) improving performance 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?	
<b>6.2 Nonconformity and corrective action</b>	When a nonconformity occurs, including any arising from complaints, has the organization:	
	a) react to the nonconformity and, as applicable:	
	1) take action to control and correct it?	
	2) deal with the consequences?	
	b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:	
	1) reviewing and analysing the nonconformity?	
	2) determining the causes of the nonconformity?	
	3) determining if similar nonconformities exist, or could	

	potentially occur?	
	c) implement any action needed?	
	d) review the effectiveness of any corrective action taken?	
	e) update risks and opportunities determined during planning, if necessary?	
	f) make changes to the quality management system, if necessary?	
<b>6.2 Nonconformity and corrective action</b>	Does corrective actions are appropriate to the effects of the nonconformities encountered?	
<b>6.2 Nonconformity and corrective action</b>	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?	
<b>6.3 Continual improvement</b>	Does the organization continually improve the suitability, adequacy and effectiveness of the quality management system?	
<b>6.3 Continual improvement</b>	Does the organization consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement?	