ISO 9001:2015 specifies requirements for a quality management system when an organization:
a) Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides**.**

Self-examination for compliance with QMS ISO 9001: 2015
The questions in the self-examination questionnaire in the following pages go through the key requirements of Quality Management System ISO 9001:2015; they are questions an organization asks itself for the specific purpose of helping organisations undertake a preliminary check of their readiness for an ISO 9001:2015 audit or assessment. This will give pointers to where an organization needs to improve. By completing this questionnaire your results will allow you to self-assess your organization and identify where you are in the implementation or transition process in relation to the main requirements of the standard. It cannot be emphasized too strongly that there are no standard ways of achieving compliance; rather there are hundreds of approaches to complying with any particular requirement. You need to focus on the requirement itself and to find the most convenient and cost-effective way to meet it in your particular situation.

With each question, mark your answers ✓ for Yes and X for No.

Yes	**We meet this requirement fully- all requisite documents and implementation requirements have been met**
No	**No we do not meet this requirement at all**

The numbers in the left hand column of the questionnaire refer to the relevant clauses in ISO 9001:2015
The higher the percentage of YES, total score on this questionnaire, the less you will have to do to become compliant.

Documented information needed to be maintained by your organisation for the purpose of establishing the QMS
(a) The scope of the QMS (clause 4.3)
(b) Documented information to support the operation of Processes (clause 4.4)
(c) The Quality Policy (clause 5)
(d) The quality objectives (clause 6.2)

NOTE: In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hardcopy or electronic, and they may be digital, analog, photographic or written.

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
Section A: Quality Management System			
4. 1 UNDERSTANDING THE ORGANISATION AND ITS CONTEXT			
a.	Have we determined the external and internal issues that are relevant to our organization's purpose and its strategic direction and those that affect our ability to achieve the Intended results of the QMS?		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
b.	Do we have a way of reviewing and monitoring these on a regular basis?		
4.2	**UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES**		
a.	Have we determined the needs and expectations of interested parties that are relevant to the Quality Management System (QMS)		
b.	Do we monitor and review this on a regular basis?		
4.3	**DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM**		
a.	**Have we determined the boundaries of the QMS when establishing its scope?** **Did we consider:** (a) external and internal issues (b) the requirements of relevant interested parties (c) our products and/or services		
b.	**Have we documented the scope?**		
c.	**Have we considered this standard and have we justified any exclusion?**		
4.4	**QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES**		
a.	**Have we determined** (a) the processes for the system and how they are to be applied? (b) the inputs and outputs for those processes? (c) how processes interrelate? (d) methods to operate, measurements and related performance indicators needed to ensure the effective operation and control of processes? (e) resources and their availability and responsibilities?		
b.	**Have we evaluated risks and opportunities, processes and their implementation;** **As necessary, have we got documented information, that gives us confidence that we are carrying out activities as planned?**		
5.0	**LEADERSHIP AND COMMITMENT**		
a.	**Can we demonstrate top management is providing leadership and commitment to the QMS including taking accountability for:** (a) The QMS (b) Policy and objectives being compatible with strategy (c) Integration of the QMS into business systems **Have the objectives been established at relevant functional, process, departmental and individual levels with the business?** (d) Promoting process approach and risk based thinking (e) Ensuring the QMS is resourced		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	(f) Communicating the QMS (g) Ensuring the QMS achieves its intended results (h) Promoting improvement (i) Supporting others		
5.1.2	**CUSTOMER FOCUS**		
a.	**Can we demonstrate that top management actively provides leadership by ensuring:** (a) customer requirements and applicable statutory and regulatory requirements are determined and met? (b) risks and opportunities that can affect the products and services are determined and addressed? (c) customer satisfaction determined, maintained and enhanced?		
5.2	**QUALITY POLICY**		
	Have we ensured the Policy (a) is appropriate to the organisation (b) has a commitment to meet requirements and continually improve the system (c) has a framework to set objectives (d) is communicated and understood (e) available as documented information (f) available to interested parties as appropriate		
5.3	**ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES**		
a.	**Have we assigned and communicated responsibilities and authorities to ensure:** (a) the QMS conforms to the standard (b) processes deliver their outputs (c) reporting on the performance of the QMS to top management (d)promotion of customer focus throughout the organization?		
6. 0	**PLANNING**		
6.1	**ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES**		
a.	**Have we determined the risks and opportunities that need to be addressed to:** (a) assure the QMS achieves its intended results (b) avoid or mitigate negative effects, enhance positive effects (c) achieve improvement **Have we planned:** (a) actions to address these risks and opportunities (b) how to integrate these actions into the QMS		
6.2.2	**In planning how to achieve our quality objectives, have we determined**		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	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**		
	Where we need to make changes to the QMS is it planned and do we consider: (a) the purpose and potential consequences (b) the integrity of the QMS (c) the availability of resources (d) changes to responsibilities and authorities		
7.0	**SUPPORT**		
7.1.1	**Resources-General** Have we determined and provided the resources needed for the QMS? Have we considered (a) the capabilities of, and constraints on existing resources (b) what needs to be obtained from external providers		
7.1.2	**People** Have we provided the persons necessary for the QMS		
7.1.3	**Infrastructure** Do we provide and maintain the necessary infrastructure (such as buildings, technology, equipment)		
7.1.4	**Environment for the operation of processes** Do we provide and maintain the environment necessary for Operations *(such as temperature, humidity, ergonomics and cleanliness).*		
7.1.5	**Monitoring and Measuring Resources** Have we 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 continued fitness for their Purpose? Have we retained appropriate documented information as evidence? Have we processes in place to (a) verify or calibrate measurement instruments against reliable standards? (b) identify measurement instruments in order to determine their calibration status? (c)safeguarded measurement instruments from adjustments, damage or deterioration? **Have corrective actions been undertaken when issues arise with measurement instruments?**		
7.1.6	**Organizational knowledge**		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	Have we determined and made available the knowledge necessary for (a) the operation of our processes and (b) achieving conformity of products and services Do we determine how to access additional knowledge for addressing change in our business?		
7.2	**Competence** Do we (a) determine the necessary competence of person(s) that could affect the QMS? (b) ensure that these person(s) are competent on the basis of appropriate education, training, or experience? (c) take actions to access the necessary competence where applicable? (d) retain appropriate documented information as evidence of competence?		
7.3	**Awareness** Have we ensured that person(s) doing work under the control of our business are aware of (a) the quality policy and relevant quality objectives (b) their contribution to the effectiveness of the QMS, including the benefits of improved quality performance (c) the implications of not conforming with the quality management system requirements		
7.4	**Communication** Have we determined the internal and external communications relevant to the QMS including: (a) what will be communicated (b) when to communicate (c) with whom to communicate (d) how to communicate (**e**) Who communicates		
7.5	**DOCUMENTED INFORMATION**		
7.5.1	**General** Does our QMS include (a) documented information required by the standard (b) documented information necessary for the effectiveness of the QMS		
7.5.2	**Creating and updating** Do we ensure we have (a) identification and description (such as a title, date, author, or reference number) (b) review and approval this include the documented scope of the Food Safety Management System?		
7.5.3	**Control of documented Information**		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	Do we ensure documented information required by the QMS are controlled to ensure: (a) it is available and suitable for use (b) it is adequately protected **Do we take into consideration these factors** (a) distribution, access, retrieval and usage (b) storage and preservation (c) version control (d) retention and disposition (e) external documents are identified as appropriate, and controlled.		
8.0.	**Operation**		
8.1	**Operational planning and control** Have we planned, implemented and controlled our processes? **Have we** (a) determined the requirements for our products and services (b) established criteria for the processes and the acceptance of products and services (c) determined the resources needed (d) implemented controls (e) retained documented information as necessary to demonstrate processes have been carried out effectively and product conformance (f) planned changes and reviewed issues, (g) ensured that outsourced processes are controlled		
8.2 **8.2.1**	**Requirements for products and services** **Customer communication** Have we established processes for communicating with customers about: (a) our products and services (b) enquiries, contracts or orders (c) feedback including complaints (d) handling their property (e) contingency processes		
8.2.2	**Determining requirements related to products and services** **For our products and services have we determined the following requirements:** (a) applicable statutory and regulatory (b) those we feel are necessary Can we meet the claims for the products and services we offer?		
8.2.3	**Review of requirements related to products and services**		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	Before committing to supply do we ensure can we meet: (a) requirements specified by the customer (b) requirements necessary for intended use (c) requirements specified by us (d) statutory and regulatory requirements (e) contract or order requirements **Do we** (a) ensure that contract or order requirements differing from those previously defined are resolved? (b) confirm requirements before acceptance of the order? (c) retain documented information as applicable describing the results of the review, including any new or changed requirements for the products and services?		
8.2.4	**Changes to requirements for products and services** **Have we** (a) ensured that documented information is amended and that relevant personnel are made aware of the changed requirements when requirements for products and services are changed?		
8.3 **8.3.1**	**Design and development of products and services** **General** Have we have a design and development process for products and services that is appropriate?		
8.3.2	**Design and Development planning** **In determining the stages and controls for design and development, have we considered:** (a) the nature, duration and complexity of the activities (b) stages including review (c) verification and validation (d) responsibilities and authorities (e) internal and external resources (f) involvement of customer and user groups (g) the subsequent production process (h) documented information required		
8.3.3	**Design and development Inputs** **Have we considered:** (a) functional and performance requirements (b) similar designs (c) statutory and regulatory requirements (d) standards or codes of practice (e) potential consequences of failure due to the nature of the products and services? **Have we ensured inputs are adequate, complete, and unambiguous and all conflicts are resolved?**		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	Have we retained documented information on design and development inputs?		
8.3.4	**Design and development controls** **Do our controls ensure** (a) the results to be achieved are defined (b) reviews are conducted to ensure designs will meet requirements? (c) verification is conducted to ensure that design outputs will meet the defined inputs (d) validation ensures products and services are capable of meeting the specified requirements or intended use (e) actions are taken on problems (f) documented information of these activities is retained.		
8.3.5	**Design and development outputs** **Have we ensured that outputs:** (a) meet the input requirements (b) are adequate for production (c) reference monitoring and measuring requirements, and acceptance criteria, as applicable (d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper use **Has documented information of outputs been retained?**		
8.3.6	**Design and development changes** Do we ensure there is no adverse impact on conformity when changes are made during design and development? Do we keep documented information on (a) design and development changes (b) results of reviews (c) authorisation of changes (d) Actions taken to prevent adverse impacts		
8.4 **8.4.1**	**Control of externally provided products and services** **General** **Do we ensure that externally provided processes, products, and services conform to specified requirements and do we apply appropriate controls when:** (a) products and services are provided by external providers for incorporation into our products and services (b) products and services are provided directly to the customer(s) by external providers on our behalf (c) a process or part of a process is provided by an external provider		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	Have we established and applied a criteria for the (a) evaluation (b) selection (c) monitoring (d) re-evaluation of external providers **Do we retain appropriate documented information?**		
8.4.2	**Type and extent of control** **Do we** (a) ensure externally provided processes are controlled within our QMS (b) define controls over the process and the output (c) consider impacts to meet statutory and client requirements (d) determine verification requirements		
8.4.3	**Information for external providers** **Have we communicated to external providers our requirements related to:** (a) the processes, products or services to be provided (b) approval or release of products and services, methods, processes or equipment (c) competence of personnel, including necessary qualifications (d) their interactions with us (e) control and monitoring we require (f) verification activities to be performed at their premises		
8.5 **8.5.1**	**Production and service provision** **Control of production and service provision** Is production undertaken under controlled conditions This may include (as applicable) (a) documented information about the products and services or activities to be performed (b) monitoring and measurement activities (c) infrastructure and environment (d) the availability and use of suitable monitoring and measuring resources (e) competent persons (f) actions to prevent errors (g) release, delivery and post-delivery activities		
8.5.2	**Identification and traceability** Do we identify outputs where it is necessary to ensure conformity? Do we identify the status of outputs? Do we control the unique identification of outputs where traceability is required? Do we retain documented information necessary to maintain traceability?		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
8.5.3	**Property belonging to customers or external providers** Do we exercise care with property belonging to the customer or external providers? Have we identified, verified, protected and safeguarded the Customer's or external provider's property? When property of the customer or external provider is lost or damaged do we report to the provider and keep documented information on what occurred? *(includes materials, components, tools and equipment, customer premises, intellectual property and personal data)*		
8.5.4	**Preservation** Do we ensure preservation of process outputs during production to maintain conformity to requirements? *(can include identification, handling, packaging, storage, transmission or transportation and protection)*		
8.5.5	**Post-delivery activities** Do we meet requirements for post-delivery activities associated with the products and services (Post-delivery activities can include warranty, contractual obligations, maintenance services, recycling or final disposal) **Do we consider:** (a) statutory and regulatory requirements (b) the potential undesired consequences associated with our products and services (c) the nature, use and intended lifetime of our products and services (d) customer requirements and feedback		
8.5.6	**Control of changes** Do we review and control changes in production to ensure continuing conformity with requirements? Do we retain documented information of the review of changes to production including authorisation and any necessary action?		
8.6	**Release of products and services** Do we have planned processes at appropriate stages of production to verify that requirements have been met? Do we ensure product is not released until this is completed? Do we retain documented information of evidence of conformity with the acceptance criteria and traceability to persons authorizing release?		
8.7	**Control of nonconforming outputs** Do we ensure product that does not conform to requirements are identified and controlled to prevent their unintended use or delivery? Do we take appropriate corrective action		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	Do we deal with nonconforming products in one or more of the following ways: (a) correction (b) segregation, containment, return or suspension of production (c) informing the customer (d) obtaining authorization for acceptance under concession Do we re-verify when products are corrected? Do we retain documented information describing the non-conformance, actions taken, concessions obtained and authorisations?		
9.0 **9.1** **9.1.1**	**PERFORMANCE EVALUATION** **Monitoring, measurement, analysis and evaluation** **General** **Have we determined** (a) what needs to be monitored and measured (b) the methods (c) when monitoring and measurement is to be done (d) when results will be analysed and evaluated Do we evaluate the effectiveness of the QMS? Do we retain documented information of this?		
9.1.2	**Customer satisfaction** Do we monitor customer perceptions *(this can include customer satisfaction surveys, customer feedback, market-share analysis, compliments, warranty claims and dealer reports)* **Have we determined how we will obtain, monitor and review this information?**		
9.1.3	**Analysis and evaluation** **Do we analyse and evaluate appropriate data?** **Do we use the results to evaluate** (a) product conformity (b) customer satisfaction (c) the performance and effectiveness of the QMS and any improvements needed (d) if planning has been implemented effectively (e) the effectiveness of actions taken to address risks and opportunities (f) external providers		
9.2 **9.2.1**	**Internal audit** **Do we conduct internal audits at planned intervals to ensure the QMS:** (a) Conforms to our requirements (b) Conforms to the requirements of 9001:2015 (c) Is effectively implemented and maintained		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
9.2.2	**Have we:** (a) planned and implemented an effective audit program (b) defined the criteria and scope for each audit (c) selected auditors to ensure objectivity and impartiality (d) ensured that the results are reported to relevant management (e) taken necessary correction and corrective actions without undue delay (f) retained documented information		
9.3 **9.3.1**	**Management Review** Does our Top management review our QMS at planned Intervals?		
9.3.2	**Do our Management Review Inputs include;** **(**a) the status of actions from previous management reviews (b) changes in external and internal issues relevant to the QMS (c) information on the QMS including − customer satisfaction and stakeholder feedback − quality objectives performance − product performance and conformity − non-conformance and corrective action − monitoring and measurement including audits − external providers − process performance and conformity of products and services; (d) adequacy of resources (e) actions taken regarding risk and opportunity (f) improvement		
	Do our Management Review Outputs include; (a) opportunities for improvement (b) changes to the QMS (c) resources **Do we retain documented information as evidence of the results of management reviews?**		
10 **10.1**	**IMPROVEMENT** **General** Have we determined and selected opportunities for improvement and implement necessary actions including: (a) improving products and services (b) correcting, preventing or reducing undesired effects; (c) improving the performance and effectiveness of the QMS		
10.2.1	**Nonconformity and Corrective action** When a nonconformity occurs, including complaints, do we: **(a) react to the nonconformity, and as applicable:**		

S No.	QMS Requirement	Score √ or x	Objective evidence (Name the document(s))
	− take action to control and correct it − deal with the consequences **(b) evaluate the need for action to eliminate the cause(s) by:** − reviewing and analysing − determining the causes − determining if similar nonconformities exist, or could potentially occur (c) implement any action needed (d) review the effectiveness of any corrective action taken (e) make changes to the QMS if necessary		
10.2.2	**Have we 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	**<u>Continual Improvement</u>** Do we (a) continually improve the effectiveness of the QMS (b) consider the outputs of analysis and management reviews to identify opportunities for continual improvement		
	Total score of Yes (√)		**Percentage % Score**
	Total score of No (x)		**Percentage % Score**
Remarks in regards to readiness for certification:			