



SRI LANKA STANDARDS INSTITUTION

ISO 9001:2015 QUALITY MANAGEMENT SYSTEM CERTIFICATION SCHEME

PRE-ASSESSMENT QUESTIONNAIREINSTRUCTIONS

- (1) The SLSI will ensure the confidentiality of all the information furnished by the applicant in this questionnaire. This information is only disclosed to the designated assessors who are required to sign a confidentiality agreement. The names of these assessors and a copy of their confidentiality agreement will be sent to the applicant prior to assessment.
- (2) Please tick (✓) the relevant box given under each question.
- (3) Upon completion of the questionnaire, it shall be returned to the Systems Certification Division of the Sri Lanka Standards Institution with the documented information maintained by the organization.

1.0 General information

1.1 Name of the Organization :

1.2 Address :

1.3 Has the organization been certified previously for ISO 9001?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

If yes ;

a. Scope of certification :

.....

.....

.....

.....

b. Date of expiry of the previous certification :

1.4 Does the organization hold any other Management Systems Certification?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

If yes ;

a. Indicate the relevant certification(s)?

- I. ISO 14001
- II. ISO 22000
- III. HACCP
- IV. OHSAS
- V. GMP

VI. Any other (please specify)

.....
.....
.....
.....
.....

b. Above certifications have been obtained from ;

I. Sri Lanka Standards Institution (SLSI)

II. Any other certification body

Yes No

1.5 Does the organization hold any Product Certification?

If yes ;

a. Please specify the certification with type of product and relevant standard.

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.....
.....
.....
.....

2.0 Context of the organization

2.1 Understanding the organization and its context

Yes No

a. Has the organization determined the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system?

b. Has the organization monitored and reviewed information about these external and internal issues?

2.2 Understanding the needs and expectations of interested parties

2.2.1 Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, has the organization determined the following?

- | | Yes | No |
|--|--------------------------|--------------------------|
| a. the interested parties that are relevant to the quality management system. | <input type="checkbox"/> | <input type="checkbox"/> |
| b. the requirements of these interested parties that are relevant to the quality management system. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.2.2 Has the organization monitored and reviewed information about these interested parties and their relevant requirements? | <input type="checkbox"/> | <input type="checkbox"/> |

2.3 Determining the scope of the quality management system

- | | Yes | No |
|--|--------------------------|--------------------------|
| 2.3.1 Has the organization determined the boundaries and applicability of the quality management system to establish its scope? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.3.2 When determining this scope, has the organization considered the following? | <input type="checkbox"/> | <input type="checkbox"/> |
| a. the external and internal issues referred to in Clause 4.1 of the ISO 9001 : 2015 Standard. | <input type="checkbox"/> | <input type="checkbox"/> |
| b. the requirements of relevant interested parties referred to in Clause 4.2 of the ISO 9001 : 2015 Standard. | <input type="checkbox"/> | <input type="checkbox"/> |
| c. the products and services of the organization. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.3.3 Has the organization applied all the requirements of the ISO 9001 : 2015 Standard if they are applicable within the determined scope of its quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.3.4 Is the scope of the organization's quality management system available, and is it maintained as documented information? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.3.5 Does the scope state the types of products and services covered, and does it provide justification for any requirement of the ISO 9001 : 2015 Standard that the organization determines not applicable to the scope of its quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |

2.4 Quality management system and its processes

- | | Yes | No |
|--|--------------------------|--------------------------|
| 2.4.1 Has the organization established, implemented, maintained and continually improved a quality management system, including the processes needed and their interactions, in accordance with the requirements of the ISO 9001 : 2015 Standard? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.4.2 Has the organization determined the processes needed for the quality management system and their application throughout the organization? | <input type="checkbox"/> | <input type="checkbox"/> |

2.4.3 Has the organization :

- | | | |
|---|--------------------------|--------------------------|
| a. determined the inputs required and the outputs expected from these processes? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. determined the sequence and interaction of these processes? | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. determined the resources needed for these processes and ensured their availability? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. assigned the responsibilities and authorities for these processes? | <input type="checkbox"/> | <input type="checkbox"/> |
| f. addressed the risks and opportunities as determined in accordance with the requirements of Clause 6.1 of the ISO 9001 : 2015 Standard? | <input type="checkbox"/> | <input type="checkbox"/> |
| g. evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results? | <input type="checkbox"/> | <input type="checkbox"/> |
| h. improved the processes and the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |

2.4.4 To the extent necessary, has the organization :

- | | | |
|--|--------------------------|--------------------------|
| a. maintained documented information to support the operation of its processes? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. retained documented information to have confidence that the processes are being carried out as planned? | <input type="checkbox"/> | <input type="checkbox"/> |

3.0 Leadership

3.1 Leadership and commitment

3.1.1 General

Has the top management demonstrated leadership and commitment with respect to the quality management system by :

- | | Yes | No |
|---|--------------------------|--------------------------|
| a. taking accountability for the effectiveness of the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |
| 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? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. ensuring the integration of the quality management system requirements into the organization's business processes? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. promoting the use of the process approach and risk-based thinking? | <input type="checkbox"/> | <input type="checkbox"/> |

- e. ensuring that the resources needed for the quality management 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?

3.1.2 Customer focus

Has the top management demonstrated leadership and commitment with respect to customer focus by ensuring 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?

3.2 Policy

3.2.1 Establishing the quality policy

Has the top management established, implemented and maintained a quality policy that :

- | | Yes | No |
|--|--------------------------|--------------------------|
| a. is appropriate to the purpose and context of the organization and supports its strategic direction? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. provides a framework for setting quality objectives? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. includes a commitment to satisfy applicable requirements? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. includes a commitment to continual improvement of the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |

3.2.2 Communicating the quality policy

Is the quality policy :

- a. available and maintained as documented information?
- b. communicated, understood and applied within the organization?
- c. made available to relevant interested parties, as appropriate?

3.3 Organizational roles, responsibilities and authorities

Yes No

3.3.1 Has the top management ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization?

3.3.2 Has the top management assigned the responsibility and authority for :

- a. ensuring that the quality management system conforms to the requirements of the ISO 9001 : 2015 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 (Clause 10.1 of the ISO 9001 : 2015 Standard), 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 ?

4.0 Planning

4.1 Actions to address risks and opportunities

4.1.1 When planning for the quality management system, has the organization considered the issues referred to in Clause 4.1 and the requirements referred to in Clause 4.2 of the ISO 9001 : 2015 Standard, and determined the risks and opportunities that need to be addressed to :

Yes No

- a. give assurance that the quality management system can achieve its intended result(s)?
- b. enhance desirable effects?

- c. prevent, or reduce, undesired effects?
- d. achieve improvement?

4.1.2 Has the organization planned :

- a. actions to address these risks and opportunities?
- b. how to :
 - 1. integrate and implement the actions into its quality management system processes (see Clause 4.4 of the ISO 9001 : 2015 Standard)?
 - 2. evaluate the effectiveness of these actions?
- c. Are the actions taken to address risks and opportunities proportionate to the potential impact on the conformity of products and services?

4.2 Quality objectives and planning to achieve them

- | | Yes | No |
|--|--------------------------|--------------------------|
| 4.2.1 Has the organization established quality objectives at relevant functions, levels and processes needed for the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |

Are the quality objectives :

- a. consistent with the quality policy?
- b. measurable?
- c. taking into account applicable requirements ?
- d. relevant to conformity of products and services and to enhancement of customer satisfaction?
- e. monitored?
- f. communicated?
- g. updated as appropriate?

Has the organization maintained documented information on the quality objectives?

- 4.2.2** When planning how to achieve its quality objectives, has the organization determined :
- a. what will be done?
 - b. what resources will be required?

- | | | |
|---------------------------------------|--------------------------|--------------------------|
| c. who will be responsible? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. when it will be completed? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. how the results will be evaluated? | <input type="checkbox"/> | <input type="checkbox"/> |

4.3 Planning of changes

When the organization determines the need for changes to the quality management system, have the changes been carried out in a planned manner (see Clause 4.4 of the ISO 9001 : 2015 Standard), considering :

- | | Yes | No |
|--|--------------------------|--------------------------|
| a. the purpose of the changes and their potential consequences? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. the integrity of the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. the availability of resources? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. the allocation or reallocation of responsibilities and authorities? | <input type="checkbox"/> | <input type="checkbox"/> |

5.0 Support

5.1 Resources

5.1.1 General

Has the organization determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system, considering :

- | | Yes | No |
|--|--------------------------|--------------------------|
| a. the capabilities of, and constraints on, existing internal resources? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. what needs to be obtained from external providers? | <input type="checkbox"/> | <input type="checkbox"/> |

5.1.2 People

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?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

5.1.3 Infrastructure

Has the organization determined, provided and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

5.1.4 Environment for the operation of processes

Has the organization determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services?

5.1.5 Monitoring and measuring resources

5.1.5.1 General

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?

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?

Has the organization retained appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources?

5.1.5.2 Measurement traceability

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, have the measuring equipment been :

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, has the basis used for calibration or verification been 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?

Does the organization determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and take appropriate action as necessary?

5.1.6 Organizational knowledge

Has the organization determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services?

Is this knowledge maintained and made available to the extent necessary?

When addressing changing needs and trends, has the organization considered its current knowledge and determined how to acquire or access any necessary additional knowledge and required updates?

5.2 Competence

Has the organization :

- | | Yes | No |
|---|--------------------------|--------------------------|
| a. determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. ensured that these persons are competent on the basis of appropriate education, training, or experience? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. where applicable, taken actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. retained appropriate documented information as evidence of competence? | <input type="checkbox"/> | <input type="checkbox"/> |

5.3 Awareness

Has the organization ensured that persons doing work under the organization's control are aware of :

- | | Yes | No |
|--|--------------------------|--------------------------|
| a. the quality policy? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. relevant quality objectives? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. the implications of not conforming with the quality management system requirements? | <input type="checkbox"/> | <input type="checkbox"/> |

5.4 Communication

Has the organization determined the internal and external communications relevant to the quality management system, including :

- | | Yes | No |
|---------------------------------|--------------------------|--------------------------|
| a. on what it will communicate? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. when to communicate? | <input type="checkbox"/> | <input type="checkbox"/> |

- | | | |
|------------------------------|--------------------------|--------------------------|
| c. with whom to communicate? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. how to communicate? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. who communicates? | <input type="checkbox"/> | <input type="checkbox"/> |

5.5 Documented information

5.5.1 General

Does the organization's quality management system include :

- | | Yes | No |
|---|--------------------------|--------------------------|
| a. documented information required by this International Standard? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. documented information determined by the organization as being necessary for the effectiveness of the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |

5.5.2 Creating and updating

When creating and updating documented information, has the organization ensured appropriate :

- | | | |
|---|--------------------------|--------------------------|
| a. identification and description (e.g. a title, date, author, or reference number)? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. format (e.g. language, software version, graphics) and media (e.g. paper, electronic)? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. review and approval for suitability and adequacy? | <input type="checkbox"/> | <input type="checkbox"/> |

5.5.3 Control of documented information

5.5.3.1 Has the documented information required by the quality management system and by the ISO 9001 : 2015 Standard been controlled to ensure :

- | | | |
|--|--------------------------|--------------------------|
| a. it is available and suitable for use, where and when it is needed? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity)? | <input type="checkbox"/> | <input type="checkbox"/> |

5.5.3.2 For the control of documented information, has the organization addressed the following activities, as applicable?

- | | | |
|---|--------------------------|--------------------------|
| a. distribution, access, retrieval and use ; | <input type="checkbox"/> | <input type="checkbox"/> |
| b. storage and preservation, including preservation of legibility ; | <input type="checkbox"/> | <input type="checkbox"/> |
| c. control of changes (e.g. version control) ; | <input type="checkbox"/> | <input type="checkbox"/> |

d. retention and disposition.

Has the documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system been identified as appropriate, and controlled?

Has the documented information retained as evidence of conformity been protected from unintended alterations?

6.0 Operation

6.1 Operational planning and control

Has the organization planned, implemented and controlled the processes (see Clause 4.4 of the ISO 9001 : 2015 Standard) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6 of the ISO 9001 : 2015 Standard), by :

- | | Yes | No |
|---|--------------------------|--------------------------|
| a. determining the requirements for the products and services? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. establishing criteria for : | | |
| 1. the processes? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. the acceptance of products and services? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. determining the resources needed to achieve conformity to the product and service requirements? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. implementing control of the processes in accordance with the criteria? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. determining, maintaining and retaining documented information to the extent necessary: | | |
| 1. to have confidence that the processes have been carried out as planned? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. to demonstrate the conformity of products and services to their requirements? | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the output of this planning suitable for the organization's operation? | <input type="checkbox"/> | <input type="checkbox"/> |
| Has the organization controlled the planned changes and reviewed the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary? | <input type="checkbox"/> | <input type="checkbox"/> |
| Has the organization ensured that outsourced processes are controlled? (see Clause 8.4 of the ISO 9001 : 2015 Standard). | <input type="checkbox"/> | <input type="checkbox"/> |

6.2 Requirements for products and services

6.2.1 Customer communication

Has the communication with customers included :

- | | Yes | No |
|--|--------------------------|--------------------------|
| a. providing information relating to products and services? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. handling enquiries, contracts or orders, including changes? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. obtaining customer feedback relating to products and services, including customer complaints? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. handling or controlling customer property? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. establishing specific requirements for contingency actions, when relevant? | <input type="checkbox"/> | <input type="checkbox"/> |

6.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, has the organization ensured that :

- | | | |
|--|--------------------------|--------------------------|
| a. the requirements for the products and services are defined, including : | | |
| 1. any applicable statutory and regulatory requirements? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. those considered necessary by the organization? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. the organization can meet the claims for the products and services it offers? | <input type="checkbox"/> | <input type="checkbox"/> |

6.2.3 Review of the requirements for products and services

- 6.2.3.1 Has the organization ensured that it has the ability to meet the requirements for products and services to be offered to customers?

Has the organization conducted a review before committing to supply products and services to a customer, to include :

- | | | |
|--|--------------------------|--------------------------|
| a. requirements specified by the customer, including the requirements for delivery and post-delivery activities? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. requirements not stated by the customer, but necessary for the specified or intended use, when known? | <input type="checkbox"/> | <input type="checkbox"/> |

- 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?

Has the organization ensured that contract or order requirements differing from those previously defined are resolved?

Are the customer's requirements confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements?

6.2.3.2 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?

6.2.4 Changes to requirements for products and services

Does the organization ensure 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?

6.3 Design and development of products and services

6.3.1 General

	Yes	No
Has the organization established, implemented and maintained a design and development process that is appropriate to ensure the subsequent provision of products and services?	<input type="checkbox"/>	<input type="checkbox"/>

6.3.2 Design and development planning

In determining the stages and controls for design and development, does the organization consider :

- 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 the 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 design and development requirements have been met?

6.3.3 Design and development inputs

Does the organization determine the requirements essential for the specific types of products and services to be designed and developed, 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. potential consequences of failure due to the nature of the products and services?

Are the inputs adequate for design and development purposes, and are they complete and unambiguous?

Are the conflicting design and development inputs resolved?

Does the organization retain documented information on design and development inputs?

6.3.4 Design and Development controls

Does the organization apply controls to the design and development process to ensure that :

- a. the results to be achieved are defined?
- b. 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?

6.3.5 Design and development outputs

Does the organization ensure 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?

Does the organization retain documented information on design and development outputs?

6.3.6 Design and development changes

Does the organization identify, review and control the changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements?

Does the organization retain documented information on :

- a. design and development changes?
- b. the results of reviews?
- c. the authorization of changes?
- d. the actions taken to prevent adverse impacts?

6.4 Control of externally provided processes, products and services

6.4.1 General

	Yes	No
Has the organization ensured that externally provided processes, products and services conform to requirements?	<input type="checkbox"/>	<input type="checkbox"/>
Has the organization determined the controls to be applied to externally provided processes, products and services when :		
a. products and services from external providers are intended for incorporation into the organization's own products and services?	<input type="checkbox"/>	<input type="checkbox"/>
b. products and services are provided directly to the customer(s) by external providers on behalf of the organization?	<input type="checkbox"/>	<input type="checkbox"/>
c. a process, or part of a process, is provided by an external provider as a result of a decision by the organization?	<input type="checkbox"/>	<input type="checkbox"/>
Has the organization determined and applied 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?	<input type="checkbox"/>	<input type="checkbox"/>
Does the organization retain documented information of these activities and any necessary actions arising from the evaluations?	<input type="checkbox"/>	<input type="checkbox"/>

6.4.2 Type and extent of control

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?	<input type="checkbox"/>	<input type="checkbox"/>
Has the organization :		
a. ensured that externally provided processes remain within the control of its quality management system?	<input type="checkbox"/>	<input type="checkbox"/>
b. defined both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output?	<input type="checkbox"/>	<input type="checkbox"/>
c. taken into consideration :		
1. the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements?	<input type="checkbox"/>	<input type="checkbox"/>
2. the effectiveness of the controls applied by the external provider?	<input type="checkbox"/>	<input type="checkbox"/>

- d. determined the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements?

6.4.3 Information for external providers

Does the organization ensure the adequacy of requirements prior to their communication to the external provider?

Does the organization communicate to external providers its requirements for:

a. the processes, products and services to be provided?

b. the approval of:

1. products and services?

2. methods, processes and equipment?

3. the release of products and services?

c. competence, including any required qualification of persons?

d. the external providers' interactions with the organization?

e. control and monitoring of the external providers' performance to be applied by the organization?

f. verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises?

6.5 Production and service provision

6.5.1 Control of production and service provision

Has the organization implemented production and service provision under controlled conditions, as applicable, with respect to :

a. the availability of documented information that defines :

1. the characteristics of the products to be produced, the services to be provided, or the activities to be performed?

2. 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 that criteria for control of processes or outputs, and 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, where 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?

6.5.2 Identification and traceability

Does the organization use suitable means to identify outputs when it is necessary to ensure the conformity of products and services?

Does the organization identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision?

Does the organization control the unique identification of the outputs when traceability is a requirement, and retain the documented information necessary to enable traceability?

6.5.3 Property belonging to customers or external providers

Does the organization exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization?

Does the organization identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services?

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, does the organization report this to the customer or external provider and retain documented information on what has occurred?

6.5.4 Preservation

Does the organization preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements?

6.5.5 Post-delivery activities

Has the organization met requirements for post-delivery activities associated with the products and services?

In determining the extent of 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?

6.5.6 Control of changes

Has the organization reviewed and controlled changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements?

Does the organization retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review?

6.6 Release of products and services

Has the organization implemented planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?

Does 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?

Does the organization retain documented information, including the following, on the release of products and services?

a. evidence of conformity with the acceptance criteria ;

b. traceability to the person(s) authorizing the release.

6.7 Control of nonconforming outputs

	Yes	No
6.7.1 Has the organization ensured that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery?	<input type="checkbox"/>	<input type="checkbox"/>

Does the organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services?

Is it applied to nonconforming products and services detected after delivery of products, during or after the provision of services?

Does the organization deal with nonconforming outputs in one or more of the following ways?

a. correction ;

b. segregation, containment, return or suspension of provision of products and services ;

c. informing the customer ;

d. obtaining authorization for acceptance under concession.

Is conformity to the requirements verified when nonconforming outputs are corrected?

6.7.2 Has the organization retained documented information that :

a. describes the nonconformity?

b. describes the action taken?

c. describes any concessions obtained?

d. identifies the authority deciding the action in respect of the nonconformity?

7.0 Performance evaluation

7.1 Monitoring, measurement, analysis and evaluation

7.1.1 General

Has the organization determined :

Yes No

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?

Has the organization evaluated the performance and the effectiveness of the quality management system?

Has the organization retained appropriate documented information as evidence of the results?

7.1.2 Customer satisfaction

Does the organization monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled?

Has the organization determined the methods for obtaining, monitoring and reviewing this information?

7.1.3 Analysis and evaluation

Does the organization analyse and evaluate appropriate data and information arising from monitoring and measurement?

Are the results of analysis 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?

7.2 Internal audit

7.2.1 Does the organization conduct internal audits at planned intervals to provide information on whether the quality management system :

a. conforms to :

Yes No

1. the organization's own requirements for its quality management system?

2. the requirements of this International Standard?

b. is effectively implemented and maintained?

7.2.2 Has the organization :

a. planned, established, implemented and maintained an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits?

- | | | |
|--|--------------------------|--------------------------|
| b. defined the audit criteria and scope for each audit? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. selected auditors and conducted audits to ensure objectivity and the impartiality of the audit process? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. ensured that the results of the audits are reported to relevant management? | <input type="checkbox"/> | <input type="checkbox"/> |
| e. taken appropriate correction and corrective actions without undue delay? | <input type="checkbox"/> | <input type="checkbox"/> |
| f. retained documented information as evidence of the implementation of the audit programme and the audit results? | <input type="checkbox"/> | <input type="checkbox"/> |

7.3 Management review

7.3.1 General

Does the 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?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

7.3.2 Management review inputs

Is the management review planned and carried out taking into consideration :

- | | | |
|---|--------------------------|--------------------------|
| a. the status of actions from previous management reviews? | <input type="checkbox"/> | <input type="checkbox"/> |
| b. changes in external and internal issues that are relevant to the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |
| c. information on the performance and effectiveness of the quality management system, including trends in : | | |
| 1. customer satisfaction and feedback from relevant interested parties? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. the extent to which quality objectives have been met? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. process performance and conformity of products and services? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. nonconformities and corrective actions? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. monitoring and measurement results? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. audit results? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. the performance of external providers? | <input type="checkbox"/> | <input type="checkbox"/> |
| d. the adequacy of resources? | <input type="checkbox"/> | <input type="checkbox"/> |

e. the effectiveness of actions taken to address risks and opportunities (see Clause 6.1 of the ISO 9001 : 2015 Standard)?

f. opportunities for improvement?

7.3.3 Management review outputs

Do 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?

c. resource needs?

Has the organization retained documented information as evidence of the results of management reviews?

8.0 Improvement

8.1 General

Has the organization determined and selected opportunities for improvement and implemented any necessary actions to meet customer requirements and enhance customer satisfaction, including :

a. improving products and services to meet requirements as well as to address future needs and expectations?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

b. correcting, preventing or reducing undesired effects?

<input type="checkbox"/>	<input type="checkbox"/>
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c. improving the performance and effectiveness of the quality management system?

<input type="checkbox"/>	<input type="checkbox"/>
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8.2 Nonconformity and corrective action

8.2.1 When a nonconformity occurs, including any arising from complaints, does the organization :

a. react to the nonconformity and, as applicable :

1. take action to control and correct it?

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

2. deal with the consequences?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

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?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

2. determining the causes of the nonconformity?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

3. determining if similar nonconformities exist, or could potentially occur?

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

- 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?
- Are the corrective actions appropriate to the effects of the nonconformities encountered?

8.2.2 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?

8.3 Continual improvement

- | | Yes | No |
|--|--------------------------|--------------------------|
| Has the organization continually improved the suitability, adequacy and effectiveness of the quality management system? | <input type="checkbox"/> | <input type="checkbox"/> |
| Has the organization considered 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? | <input type="checkbox"/> | <input type="checkbox"/> |