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| **CHAPTER OF STANDARD: 4. Context of The Organization** | | | | |
| **4.1 Understanding the organization** | | | | |
| Requirement / subject | Stage 1 | E | Stage 2 | E |
| The organization shall monitor and review information about these external and internal issues:  The organization shall monitor and review information about these external and internal issues;  Please list the issue covering climate change and its implementation |  |  | The organization has documented its Quality Manual (Ref: {{ manual\_number }}date: {{ manual\_date }}).  The organization procedure was verified in quality manual annexure number Ref: {{ procedure\_number }} on this date: {{ manual\_date }}  Internal and external issues relevant to the QMS are identified in Ref: {{ INTERNAL\_ISSUE\_NO|safe }}.  Internal Issue:  {{ INTERNAL\_ISSUE }}  External Issue:  {{ EXTERNAL\_ISSUE}} | S |
| **4.2 Understanding the needs and expectations of interested parties** | | | | |
| the organization shall determine:  a) the interested parties that are relevant to the quality management system;  b) the requirements of these interested parties that are relevant to the quality management system |  |  | The organization Needs and expectations of interested parties (Ref: {{ interested\_parties\_NO}}) are adequately identified.  One of the interested parties is verified  Interested Parties:  {{ interested\_parties}} |  |

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| **4.3 Determining the scope of the quality management system** | | | | | |
| determining this scope, the organization shall consider:  a) the external and internal issues.  b) requirements of relevant interested parties  c) products and services of the organization |  |  | Organization: {{ Organization\_Name }}. Address: {{ Address }}  Temp. add: {{ Temp\_Address }}  .  Scope: {{Scope\_s}} | | S |
| **4.4 Quality management system and its processes** | | | | | |
| **4.4.1**  determining this scope, the organization shall consider:  a) determine the inputs required and the outputs expected from these processes;  b) determine the sequence and interaction of these processes;  c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;  d) determine the resources needed for these processes and ensure their availability;  e) assign the responsibilities and authorities for these processes;  f) address the risks and opportunities as determined in accordance with the requirements of 6.1;  g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results:  h) improve the processes and the quality management system |  |  | The organization's processes are clearly outlined and verified in the Quality Manual, Reference: {{ manual\_number }}  {{ PROCESS }}  All processes are governed by Standard Operating Procedures (SOPs) and checklists, as detailed and verified in Document No.{{ procedure\_number }}, effective from {{ manual\_date }}. | S | |
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| **4.4.2** | | | | | |
| To the extent necessary, the organization shall:  a) maintain documented information to support the operation of its processes;  b) Retain documented information to have confidence that the processes are being carried out as planned. |  |  | {{ Documented\_information }} | | S |
| **5. Leadership** | | | | | |
| **5.1. Leadership and commitment** | | | | | |
| **Genera** | | | | | |
| Top management shall demonstrate 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 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 |  |  | Top management commitment evident through management review, resource provision, and risk-based approach. Documents seen: MRM records, risk register. | | S |
| **5.1.2 Customer focus** | | | | | |  |  | The job fKLTtion of Mr. akhtar khan designation Machine man and roles are defined in Ref:-ASE /RR/ D-01. |
| management shall demonstrate 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. |  |  | Top management showed customer focus by determining and meeting customer, statutory, and regulatory requirements. Risk and opportunity registers were reviewed, and actions for customer satisfaction enhancement were evident. Management maintains focus on ensuring product conformity and timely delivery. | | S |
| **5.2 Policy** | | | | | |
| **5.2.1 Establishing the quality policy** |  |  |  |  | |
| Top management shall establish, implement and maintain a quality policy that: 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 |  |  | A quality policy is established, documented, and aligned with the strategic direction of the organization. The policy supports the setting of quality objectives and reflects commitments to compliance and continual improvement. Policy content is found to be appropriate and relevant to organizational purpose. | | S |
| **5.2.2 Communicating the quality policy** | | | | | |
| The quality policy shall:  a) be available and be maintained as documented information;  b) be communicated, understood and applied within the organization;  c) Be available to relevant interested parties, as appropriate. |  |  | The quality policy is displayed at key locations, available in documented information, and communicated during awareness sessions. Employees interviewed were generally aware of the policy. Policy is also shared with relevant stakeholders as needed. | | S |
| **5.3 Organizational roles, responsibilities and authorities** | | | | | |
| Top management shall 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. |  |  | Roles, responsibilities, and authorities are defined in organizational charts, job descriptions, and QMS procedures. Evidence confirms responsibility for QMS conformity, process performance, and customer focus is assigned.  Documents seen: Org. chart, job descriptions. | |  |
| **6. Planning** | | | | | |
| **6.1. Actions to address risks and opportunities.**  determine the risks and opportunities that need to be addressed to:  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 achieve improvement. |  |  | The organization risk register is verified with mitigation plan record was evident in this documents number Ref: {{ risk\_register\_NO }}  {{ risk\_AND\_MITIGATION}} | | S |
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| **6.1 .2** | | | | | |
| a) actions to address these risks and opportunities;  b) how to:  1) integrate and implement the actions into its quality management system processes (see 4.4);  2) Evaluate the effectiveness of these actions. |  |  | {{ actions\_to\_address\_these\_risks\_and\_opportunities }} | S | |
| **6.2 Quality objectives and planning to achieve them** | | | | | |
| **6.2.1** |  |  | Quality objectives (Ref: {{ objective\_NO }}) one of the quality objective are given below-  {{ QUALITY\_OBJECTIVE\_CO }} | | S |
| The quality objectives shall:  a) be consistent with the quality policy;  b) be measurable;  c) take into account applicable requirements;  d) be relevant to conformity of products and services and to enhancement of customer satisfaction;  e) be monitored;  f) be communicated;  g) be updated as appropriate |
| **6.2.2** |  |  |  | |
| how to achieve its quality objectives, the organization shall determine:  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 |  |  | The organization ensures quality objectives are achievable by defining clear actions, allocating resources, assigning responsibilities, and setting timelines. Progress is tracked and results are evaluated through KPIs and management reviews to confirm effectiveness.  Documents seen: Quality objectives plan, action tracker, MRM records. | |
| **6.3 Planning of changes** | | | | | |
| The organization shall consider:  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 |  |  | The organization changes to the QMS are planned considering their purpose, potential impact, resource availability, and assigned responsibilities to maintain system integrity.  Documents seen: Change records, management review minutes, responsibility matrix. | | S |
| **7 Support** | | | | | |
| **7.1 Resources** |  |  | The organization has effectively evaluated internal resource capabilities and limitations. Requirements for additional resources from external providers are identified and procured as needed to support the QMS and ensure process effectiveness.  Documents seen: Resource planning records, procurement records, management review minutes. | | S |
| **7.1.1 General** |
| The organization shall consider:  a) the capabilities of, and constraints on, existing internal resources;  b) What needs to be obtained from external providers? |
| **7.1.2 People** | | | | | |
| Shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes. |  |  | The organization has determined and provided competent personnel required for effective QMS implementation and process operations. Training and competency records confirm adequacy.  Documents seen: Manpower plan, training matrix, competency records. | | S |
| **7.1.3 Infrastructure** | | | | | |
| Infrastructure can include:  a)   buildings and associated utilities;  b)   equipment, including hardware and software; c)   transportation resources;  d)   information and communication technology |  |  | Adequate infrastructure is maintained, including buildings, utilities, equipment, IT systems, and transportation facilities, to support QMS operations. Preventive maintenance and calibration are carried out regularly.  Documents seen: Asset register, calibration certificates, maintenance records. | |  |
| **7.1.4 Environment for the operation of processes** |  | | | | |
| A suitable environment can be a combination of human and physical factors, such as:  a) social  (e.g. non-discriminatory, calm, non-confrontational);  b)   psychological (e.g. stress, burnout prevention, emotionally protective);  c)   Physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). |  |  | A suitable working environment is maintained through proper physical conditions (temperature, ventilation, hygiene), and supportive social/psychological factors to ensure effective process operations.  Documents seen: Workplace safety inspections, housekeeping records. | S | |
| **7.1.5 Monitoring and measuring resources** | | | | | |
| **7.1.5.1 General** |  |  | {{ Monitoring\_and\_measuring\_resources }} | | S |
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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **7.1.5.2 Measurement traceability** | | | | | | | a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be 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. |  |  | {{ Measurement\_traceability }} |  | | | **7.1.6 Organizational knowledge** | | | | | | | Organizational knowledge can be based on:  a)   internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience;  the results of improvements in processes, products and services);  b)   external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers) |  |  | Organizational knowledge is maintained from internal sources (lessons learned, process improvements) and external sources (standards, customer feedback, conferences) to support QMS effectiveness.  Documents seen: Lessons learned records, process improvement reports, training records, standards references. | |  |   **7.1.5.2 Measurement traceability** | | | | | | | | |
| **7.2 Competence** | | | | | | | |  |
| 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 |  | |  | | | | {{ Competence }} |
| **7.3 Awareness** | | | | | | | | |
| 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;  d) The implications of not conforming with the quality management system requirements. |  | | | |  | The organization ensures that all personnel are aware of the quality policy and relevant quality objectives, understand their role and contribution to the effectiveness of the QMS and the consequences of non-conformity. Awareness programs and trainings are conducted regularly.  Documents seen: Training records, induction materials, communication logs, meeting minutes. | |  |
| **7.4 Communication** | | | | | | | | |
| a) on what it will communicate;  b) when to communicate;  c) with whom to communicate;  d) how to communicate;  e) Who communicates? |  | | | |  | The organization has established clear communication processes to share QMS-related information internally and externally. Methods include meetings, toolbox talks, emails, and notice boards. Communication roles and timing are defined to ensure important quality information is delivered effectively.  These evidences are verified during the assessment.  Communication plan, meeting minutes, emails, notice boards, internal memos. | |  |
| **7.5 Documented information** | | | | | | | | |
| **7.5.1 General** |  | | | |  | The QMS includes all documented information required by ISO 9001 and additional documents deemed necessary for system effectiveness.  Documents seen: QMS manual, procedures, work instructions, forms. | |  |
| organization’s quality management system shall 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. |
| **7.5.2 Creating and updating** | | | | | | | | |
| a) identification and description (e.g. a title, date, author, or reference number);  b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);  c) review and approval for suitability and adequacy. |  | | | |  | Documented information is properly identified, described, formatted, and reviewed/approved for suitability and adequacy before release.  Documents seen: Document control records, approval sheets, version history logs. | |  |
| **7.5.3 Control of documented information** | | | | | | | | |
| **7.5.3.1 Documented information required** |  | | | |  | Documents are available where needed, accessible to relevant personnel, and adequately protected from loss, misuse, or unauthorized changes and managing by master list of formats.  Documents seen: Document repository, access controls, backup records. | |  |
| a) it is available and suitable for use, where and when it is needed;  b) It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). |
| **7.5.3.2 control of documented information** | | | | | | | | |
| a) distribution, access, retrieval and use;  b) storage and preservation, including preservation of legibility;  c) control of changes (e.g. version control);  d) retention and disposition |  | | | |  | {{ Control\_of\_documented\_information }} | |  |
| **8 Operation** |  | | | |  |  | |  |
| **8.1 Operational planning and control** |  | | | |  | The organization's processes are clearly outlined and verified in the Quality Manual, Reference: {{ manual\_number }}  {{ PROCESS }}  All processes are governed by Standard Operating Procedures (SOPs) and checklists, as detailed and verified in Document No.{{ procedure\_number }}, effective from {{ manual\_date }}.  {{ Operational\_planning\_and\_control }} | |  |
| a) determining the requirements for the products and services;  b) establishing criteria for:  1) the processes;  2) 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:  1) to have confidence that the processes have been carried out as planned;  2) To demonstrate the conformity of products and services to their requirements. |
| **8.2 Requirements for products and services** | | | | | | | | |
| **8.2.1 Customer communication** |  | | | |  | {{ Customer\_communication }} | |  |
| Communication with customers shall include:   1. providing information relating to products and services; 2. handling enquiries, contracts or orders, including changes; 3. obtaining customer feedback relating to products and services, including customer complaints; 4. handling or controlling customer property; 5. Establishing specific requirements for contingency actions, when relevant. |
| **8.2.2 determining the requirements for products and services** |  | | | |  |  | |  |
| When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:   1. the requirements for the products and services are defined, including:    1. any applicable statutory and regulatory requirements;    2. those considered necessary by the organization; 2. The organization can meet the claims for the products and services it offers. |  | | | |  | Organization: {{ Organization\_Name }}. Address: {{ Address }}  Temp.add: {{ Temp\_Address }}  .  The organization legal register was verified on Ref: {{ legal\_REGISTER\_NO }} evident.  {{ legal\_LICENSE }} | |  |
| **8.2.3.1 review of the requirements for products and services** | | | | | | | | |
| a) requirements specified by the customer, including the 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. |  | | |  | | {{ review\_of\_the\_requirements\_for\_products\_and\_services }} | |  |
| **8.3 Design and development of products and services** |  | | | | | | | |
| **8.3.1 General** | **N/A** | | |  | | {{ Design\_and\_development\_of\_products\_and\_services }} | |  |
| Establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. |
| **8.3.2 Design and development planning** | | | | | | | | |
| 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. | | **N/A** | |  | | {{ Design\_and\_development\_planning }} | |  |
| **8.3.3 Design and development inputs** | | | | | | | |  |
| Organization 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. | | **N/A** | |  | | {{ Design\_and\_development\_inputs }} | |  |
| **8.3.4 Design and development controls** | |  | |  | |  | |  |
| 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. | | **N/A** | |  | | {{ Design\_and\_development\_controls }} | |  |
| **8.3.5 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. | | **N/A** | |  | | {{ Design\_and\_development\_outputs }} | |  |
| **8.3.6 Design and development changes** | |  | |  | |  | |  |
| The organization shall retain documented information on:  a) design and development changes;  b) the results of reviews;  c) the authorization of the changes;  d) the actions taken to prevent adverse impacts. | | **N/A** | |  | | {{ Design\_and\_development\_changes }} | |  |
| **8.4 Control of externally provided processes, products and services** | | | | | | | | |
| **8.4.1 General** | |  | |  | |  | |  |
| a) products and services from external providers are intended for incorporation into the organization’s own products and services;  b) 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. | |  | |  | | {{ Control\_of\_externally\_provided\_processes\_products\_and\_services }} | |  |
| **8.4.2 Type and extent of control** | |  | |  | |  | |  |
| The organization shall:  a) ensure that externally provided processes remain within the control of its quality management system;  b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;  c) take 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;  2) the effectiveness of the controls applied by the external provider;  d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. | |  | |  | | {{ Type\_and\_extent\_of\_control }} | |  |
| **8.4.3 Information for external providers** | |  | |  | |  | |  |
| The organization shall 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. | |  | |  | | {{ Information\_for\_external\_providers }} | |  |
| **8.5 Production and service provision** | | | | | | | | |
| **8.5.1 Control of production and service provision** | |  | |  | |  | |  |
| Controlled conditions shall include, as applicable:  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. | |  | |  | | Production and service provision are carried out under controlled conditions. Documented information defines product/service characteristics and expected results. Monitoring, measurement, competent personnel, suitable infrastructure, error prevention, and validation activities are implemented. Release, delivery, and post-delivery activities are also controlled.  Documents seen: Work instructions, process monitoring records, calibration records, competency records, validation reports, release records. | |  |
| **8.5.2 Identification and traceability** | | | | | | | | |
| shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision  control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability | |  | |  | | {{ Identification\_and\_traceability }} | |  |
| **8.5.3 Property belonging to customers or external providers** | | | |  | | | | |
| shall exercise care with property belonging to customers or external providers while it is under the organization’s control  shall identify, verify, protect and safeguard customers’ or external providers’ property provided for use or incorporation into the products and services  property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred. | |  | |  | | {{ Property\_belonging\_to\_customers\_or\_external\_providers }} | |  |
| **8.5.4 Preservation** | | | | | | | | |
| Shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. | |  | |  | | Outputs during production and service provision are preserved appropriately to ensure conformity to specified requirements, including handling, storage, packaging, and transportation controls.  Documents seen: Preservation procedures, handling instructions, storage records, packaging guidelines. | |  |
| **8.5.5 Post-delivery activities** | |  | |  | |  | |  |
| In determining the extent of post-delivery activities that are required, the organization shall consider:  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. | |  | |  | | The organization determines the extent of post-delivery activities by considering statutory/regulatory requirements, potential undesired consequences, product/service nature, intended lifetime, customer requirements, and feedback.  Documents seen: Post-delivery procedure, customer feedback records, warranty/maintenance logs, compliance records. | |  |
| **8.5.6 Control of changes** | | | | | | | | |
| Shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.  The organization shall 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 | |  | |  | | {{ Control\_of\_changes }} | |  |
| **8.6 Release of products and services** | |  | |  | |  | |  |
| The documented information shall include:  a) Evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release. | |  | |  | | {{ Release\_of\_products\_and\_services }} | |  |
| **8.7.1 Control of nonconforming outputs** | |  | |  | |  | |  |
| The organization shall 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. Conformity to the requirements shall be verified when nonconforming outputs are corrected.  **8.7.2**  The organization shall retain 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 | |  | |  | | {{ Control\_of\_nonconforming\_outputs }} | |  |
| **9 Performance evaluation** | | | | | | | | |
| **9.1. Monitoring, measurement, analysis and evaluation** | |  | |  | |  | |  |
| **9.1.1 General** | |  | |  | |  | |  |
| 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 analyzed and evaluated. | |  | |  | | {{ Monitoring\_measurement\_analysis\_and\_evaluation }} | |  |
| **9.1.2 Customer satisfaction** | | | | | | | |  |
| shall monitor customers’ perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. | |  | |  | | The organization monitors customer perceptions to determine the extent to which their needs and expectations are met. Methods for obtaining, monitoring, and reviewing customer feedback are defined and implemented.  Documents seen: Customer feedback records, surveys, complaint logs, review reports. | |  |
| **9.1.3 Analysis and evaluation** | | | | | | | | |
| The results of analysis shall be 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. | |  | |  | | Analysis results are used to evaluate product/service conformity, customer satisfaction, QMS performance and effectiveness, effectiveness of risk and opportunity actions, external provider performance, and to identify opportunities for improvement.  Documents seen: Management review minutes, KPI reports, internal audit reports, supplier performance records, corrective action reports. | |  |
| **9.2 Internal audit** | | | | | | | | |
| **9.2.1** | |  | |  | | The organization conducts an internal audit annually, with records verified in Ref: {{ Internal\_Audit\_NO }}on {{ Internal\_Audit\_Date }}  Internal Audit:  Internal Audit Number: {{ Internal\_Audit\_NO }}  Audit Date: {{ Internal\_Audit\_Date }}  Audit Frequency: Annually  Internal Auditor Name: {{ Internal\_Auditor\_name }}  Auditor’s Qualification: {{ Auditor\_Qualification }} | |  |
| The organization shall conduct internal audits at planned intervals to provide information:  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. | |
| **9.2.2** | |  | |  | |  | |  |
| a) plan, establish, implement and maintain an audit program(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) define the audit criteria and scope for each audit;  c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;  d) ensure that the results of the audits are reported to relevant management;  e) take appropriate correction and corrective actions without undue  delay;  f) Retain documented information as evidence of the implementation of the audit programmer and the audit results. | |  | |  | | Internal Audit Findings:  During the audit, {{ Internal\_Auditor\_name }} identified one minor non-conformity and several observations.  {{ Non\_conformity }} | |  |
| **9.3 Management review** | | | | | | | | |
| **9.3.1 General** | |  | |  | |  | |  |
| Shall 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. | |  | |  | | Management Review Meeting (MRM):  The MRM was conducted on {{ MRM\_Date }}  MRM Agenda:  {{ MRM\_Agenda }}  Records of the MRM are verified in document Ref: {{ MRM\_NO }} and approved by the authorized person | |  |
| **9.3.2 Management review inputs** | | | | | | | |  |
| 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 (see 6.1);  f) Opportunities for improvement. | |  | |  | | Organization reviews previous actions, internal/external changes, QMS performance (customer satisfaction, objectives, NCs, audits, suppliers), resources, risks & opportunities, and improvement needs.  Documents seen: Review agenda, minutes, KPI reports, audits, feedback, supplier evaluations. | |  |
| **9.3.3 Management review outputs** | | | | | | | |  |
| a) opportunities for improvement;  b) Any need for changes to the quality management system; c) resource needs. | |  | | |  | | Management review outputs address opportunities for improvement, the need for changes to the QMS, and resource requirements for sustaining system effectiveness. Documents seen: Management review minutes, action plan tracker, resource allocation records. |  |
| **10 Improvement** | |  | | | | | |  |
| These shall include:  a) improving products and services to meet requirements as well as to address future needs and expectations;  b) correcting, preventing or read undesired effects;  c) improving the performance and effectiveness of the quality management system. | |  | | |  | | The organization demonstrates continual improvement by enhancing products and services to meet current and future requirements, addressing nonconformities and undesired effects through corrective and preventive measures, and improving overall QMS performance and effectiveness. Documents seen: CAPA records, continual improvement projects, customer feedback reports, process enhancement initiatives. |  |
| **10.2 Nonconformity and corrective action** | | | | | | | |  |
| the organization shall:  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 analyzing 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. | |  | | |  | | {{ Nonconformity\_and\_corrective\_action }} |  |
| **10.2.2** | |  | | |  | |  |  |
| shall retain documented information as evidence of:  a) the nature of the nonconformities and any subsequent actions taken;  b) the results of any corrective action. | |  | | |  | | The organization retains documented evidence of nonconformities, actions taken, and results of corrective actions to ensure effective closure.  Documents seen: NC log, CAPA records, corrective action reports. |  |
| **10.3 Continual improvement** | | | | |  | |  |  |
| shall continually improve the suitability, adequacy and effectiveness of the quality management system  shall 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. | |  | | | The organization demonstrates continual improvement of QMS suitability, adequacy, and effectiveness by using analysis, evaluation, and management review outputs to identify and act on opportunities.  Documents seen: Improvement plans, MRM outputs, KPI analysis, process improvement records. |  |
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