| Requirement | Findings | Y/N |
| --- | --- | --- |
| 4 Context Of Your Company |  |  |
| 4.1 Understand Your Company and Its Context |  |  |
| Your Company has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect our ability to achieve the intended results of its quality management system. |  |  |
| Your Company shall monitor and review information about these external and internal issues. |  |  |
| 4.2 Understanding the Needs and Expectations of Interested Parties |  |  |
| Due to the effect or potential effect on Your Company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements. |  |  |
| Your Company shall determine:   * the interested parties that are relevant to the quality management system; * the requirements of these interested parties that are relevant to the quality management system. |  |  |
| The Your Company monitors and reviews information about these interested parties and their relevant requirements. |  |  |
| 4.3 Determining the Scope of the Quality Management System |  |  |
| Your Company shall/has determined the boundaries and applicability of the quality management system to establish its scope. |  |  |
| When determining the scope, the Your Company has considered:   * the external and internal issues referred to in 4.1; * the requirements of relevant interested parties referred to in 4.2; * the products and services of Your Company. |  |  |
| Your Company shall apply all the requirements of this international standard if they are applicable within the determined scope of its quality management system. |  |  |
| The scope of Your Company's quality management system shall be available and be **maintained as documented information**. The scope shall state the types of products and services covered and provide justification for any requirements of the standard that Your Company determines is not applicable to the scope of its quality management system. These are described in 1.2. |  |  |
| Conformity to the standard may only be claimed if the requirements determined do not affect the Your Company's ability or responsibility to ensure the conformity of its products and services and enhancement of customer satisfaction. |  |  |
| 4.4 Quality Management System and Its Processes |  |  |
| 4.4.1 |  |  |
| Your Company has established, implemented, maintains and continually improves our quality management system, including the processes needed and their interactions, in accordance with the requirements of the standard. |  |  |
| Your Company shall determine the processes needed for the quality management system and their application throughout Your Company and shall:   * determine the inputs required and the outputs expected from these processes; * determine the sequence and interaction of these processes; * 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; * determine the resources needed for these processes and ensure their availability; * assign the responsibilities and authorities for these processes; * address the risks and opportunities as determined in accordance with the requirements of 6.1; * evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; * improve the processes and the quality management system. |  |  |
| 4.4.2 |  |  |
| To the extent necessary, Your Company shall:   * **maintain documented information** to support the operation of its processes; * **retain documented information** to have confidence that the processes are being carried out as planned. |  |  |
| 5 Leadership |  |  |
| 5.1 Leadership and Commitment |  |  |
| 5.1.1 General |  |  |
| Top management shall demonstrate leadership and commitment with the respect to the quality manager of system by:   * Taking accountability for the effectiveness of the quality management system; * 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 Your Company: * Ensuring the integration of the quality management system requirements into Your Company's business processes; * Promoting the use of the process approach and [miss-spaced 00:00:49] thinking; * Ensuring that the results is measured for quality management system are available; * Communicating the importance of effective quality management and of conforming to the quality management system requirements; * Ensuring the quality management system achieves its intended results; * Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; * Promoting improvement; * Promoting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.. |  |  |
| References to Business in this manual can be broaden to mean as activities that are core to the purposes of Your Company's existence whether Your Company is public, private, for profit or not for profit. |  |  |
| 5.1.2 Customer Focus |  |  |
| Top management has demonstrated leadership and commitment with respect to customer focus by ensuring that:   * Customer and applicable statutory and regulatory requirements are determined, understood and consistently met; * The risks and opportunities can affect the conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; * The practice on enhancing customer satisfaction is maintained. |  |  |
| 5.2 Policy |  |  |
| 5.2.1 Establishing the quality policy |  |  |
| Top management shall establish, implement and maintain a quality policy that:   * Is appropriate to the purpose and context of Your Company and supports its strategic directions; * Provides a framework for setting quality objectives; * Includes a commitment to satisfy applicable requirements; * Includes a commitment to continue with improvement of the quality management system. |  |  |
| 5.2.2 Communicating the quality policy |  |  |
| The quality policy shall:   * Be available and be **maintained as documented information**; * Be communicated, understood and applied within Your Company; * Be available to relevant interested parties, as appropriate. |  |  |
| 5.3 Organizational roles, Responsibilities and Authorities |  |  |
| Top management has ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within Your Company. |  |  |
| Top management has assigned the responsibility and the authority for:   * Ensuring that the quality management system conforms to the requirements of the standard; * Ensuring that the processes are delivering their intended output; * Reporting on the performance of the quality management system and on opportunities for improvement, in particular to Top management in 10.1; * Ensuring the promotion of customer focus throughout organization; * Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. |  |  |
| 6 Planning |  |  |
| 6.1 Actions to address risks and opportunities |  |  |
| 6.1.1 |  |  |
| When planning for the quality management system, Your Company has considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:   * Give assurance that the quality management system can achieve it's intended result(s); * Enhanced desirable affects; * Prevent, or reduce, undesired affects; * Achieve improvement. |  |  |
| 6.1.2 |  |  |
| Your Company has planned:   * How to:   + Integrate and implement the actions into its quality management system processes, see 4.4;   + Evaluate the [inaudible 00:01:30] of those actions. |  |  |
| Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. |  |  |
| Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood of consequences, sharing the risk, or retaining risk by informed decision. |  |  |
| Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address Your Company's or it's customer's needs. |  |  |
| 6.2 Quality objectives and planning to achieve them |  |  |
| 6.2.1 |  |  |
| Your Company has established the quality objectives at relevant functions, levels and processes needed for the quality management system. |  |  |
| The quality objectives are:   * Consistent with the quality policies; * Measurable; * Take into account applicable climate; * Be relevant to conformity of products and services and to enhancement of customer satisfaction; * Are monitored; * Communicated; * Updated as appropriate.   Your Company shall **maintain documented information** on the quality objectives. |  |  |
| 6.2.2 |  |  |
| When planning how to achieve its quality objectives, Your Company has determined:   * What will be done; * What resources will be required; * Who will be responsible; * When it will be completed; * How the results will be evaluated. |  |  |
| 6.3 Planning of Changes |  |  |
| Your Company determines the needs for changes to the quality management system, the changes are carried out in a planned manner (see 4.4). |  |  |
| Your Company shall consider:   * The purpose of the changes and the potential consequences; * The integrity of the quality management system; * The availability of resources; * The allocation or reallocation of responsibilities and authorities. |  |  |
| 7 Support |  |  |
| 7.1 Resources |  |  |
| 7.1.1 General |  |  |
| Your Company shall determine and provide the resources noted for the establishment, implementation, maintenance and continual improvement of the quality management system. |  |  |
| Your Company has considered:   * The capabilities of, and constraints on, existing internal resources; * What needs to be obtained from external providers. |  |  |
| 7.1.2 People |  |  |
| Your Company has determined and provided the [inaudible 00:00:54] persons necessary for the effective implementation of its quality management system and for the proper operation and control of this process. |  |  |
| 7.1.3 Infrastructure |  |  |
| Your Company shall determine, provide, and maintain the infrastructure necessary for the operation of this processes and to achieve conformity in products and services. Note: Infrastructure can include but not limited to buildings and associated utilities; equipment including hardware and software. Transportation resources. Information and communication technology. |  |  |
| 7.1.4 Environment for the Operational Processes |  |  |
| Your Company shall determine, provide and maintain the environment necessary of the operational process and to achieve conformity of products and services. Note: A suitable environment can be accommodation of a few physical factors such as social [calm, non-confrontational], psychological, [eg. Stress reducing, brand app prevention, emotionally protective], physical [eg. Temperature, light, humidity, air-flow, hygiene, noise]. These factors can differ substantial depending on the products and services provided. |  |  |
| 7.1.5 Monitoring and Measuring Resources |  |  |
| 7.1.5.1 General |  |  |
| Your Company shall determine and provide the resources to ensure valid and reliable results. When monitoring or measuring it's used to verify the conformity of products and services to requirements. |  |  |
| Your Company shall ensure that the resources provided:   * Suitable for the specific type of monitoring and measurement activities being undertaken; * Are maintained to ensure their continuing fitness for purpose.   Your Company shall **retain appropriate documented information** as evidence of fitness of purpose or a monitoring and measurement resources. |  |  |
| 7.1.5.2 Measurement and Measurement Traceability |  |  |
| When Measurement Traceability is a requirement, or is considered by Your Company to be essential part of providing confidence in the validity of measurement results. Measurement equipment shall be:   * 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 exists, the basis used for calibration verification shall be **retained as documented information**. * Identified in order to determine their status: Typical * Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. |  |  |
| Your Company shall determine if the validity of previous measurement results has been adversely effected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary. |  |  |
| 7.1.6 Organizational Knowledge |  |  |
| Your Company shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. |  |  |
| When addressing changing needs and trends, Your Company shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. Note: Organizational knowledge is knowledge specific to Your Company. It is generally gained by experience. It is information that is used and shared to achieve Your Company’s objectives. |  |  |
| Organizational knowledge can be based on internal resources such as; intellectual property, knowledge gained from experience, lessons learned from failures, and successful projects. Capturing and sharing out and documented knowledge and experience the results of improvements in processes and products and services. And external sources such as; standards, academia, conferences, gathering knowledge from customers or external providers. |  |  |
| 7.2 Competence |  |  |
| Your Company has:   * Determined the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management systems; * Ensure that these persons are competent on the basis of appropriate education, training or experience; * Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; * **Retain appropriate documented information** as evidence of competence.   Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons. |  |  |
| 7.3 Awareness |  |  |
| Your Company ensures that persons doing work under Your Company's control are aware of:   * The quality policy; * Relevant quality objectives; * Their contribution to the effectiveness of the quality management system, including the benefits of improved performance; * The implications of not confirming with the quality management system requirements. |  |  |
| 7.4 Communication |  |  |
| Your Company has determined the internal and external communications relevant to the quality manual system, including:   * On what it will communicate; * When to communicate; * With whom to communicate; * How to communicate; * Who communicates. |  |  |
| 7.5 Documented Information |  |  |
| 7.5.1 General |  |  |
| Your Company's quality management system includes:   * Documented information required by the standard; * Documented information determined by Your Company as being necessary for the effectiveness of the quality management system. |  |  |
| The extent of document information for a quality management system is different from one organization to another due to the size of Your Company's type of activities processes, products and services; the complexity of processes and their interaction and the competence of persons. |  |  |
| 7.5.2 Creating and Updating |  |  |
| When creating and updating documented information Your Company ensures appropriate:   * Identification and description (e.g. a title, date, author or reference number); * Format (e.g. language, software version, graphics) and media (e.g. paper, electronic); * Review and approval for suitability and adequacy. |  |  |
| 7.5.3 Control of Documented Information |  |  |
| 7.5.3.1 |  |  |
| Document information required by the quality management system and by the standard is controlled to ensure:   * It is available and suitable for use where and when it is needed; * It is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). |  |  |
| 7.5.3.2 |  |  |
| For the control of documented information, Your Company has addressed the following activities as applicable:   * Distribution, access, retrieval and use; * Storage and preservation, including preservation of legibility; * Control of changes (e.g. version control); * Retention and disposition of documented information of external origin determined by Your Company to be necessary for the planning and operation of the quality management system shall be identified as appropriate and be controlled. * Documented information retained as evidence of conformity shall be protected from unintended alterations. |  |  |
| Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information. |  |  |
| 8 Operations |  |  |
| 8.1 Operational Planning and Control |  |  |
| Your Company plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6 by:   * Determine the requirements for the products and services; * Establishing criteria for the processes and the acceptance of products and services; * Determining the resources needed to achieve conformity to product and service requirements; * Implementing control of the processes in accordance with the criteria; * 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.   * The output of this planning shall be suitable for Your Company's operations. |  |  |
| Your Company shall control plan changes and review the necessary consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. Your Company shall ensure that outsourced processes are controlled (see 8.4). |  |  |
| 8.2 Requirements for products and services |  |  |
| 8.2.1 Customer communication |  |  |
| Communication with customers shall include:   * Providing the information relating to products and services; * Handling enquiries, contracts or orders, including changes; * Containing customer feedback related to products and services, including customer complaints; * Handling or controlling customer product; * 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, Your Company shall ensure that:   * The requirements for the products and services are defined, including:  1. Any applicable statutory and regulatory requirements; 2. Those considered necessary by Your Company;  * Your Company can meet the claims for products and services it offers. |  |  |
| 8.2.3 Review of the requirements for products and services |  |  |
| 8.2.3.1 |  |  |
| Your Company ensures that it has the ability to meet the requirements for products and services to be offered to customers. |  |  |
| Your Company conducts a review before committing to supply products and service to a customer, to include:   * Requirements specified by the customer, including the requirements for delivery and post-delivery activities; * Requirements not stated by the customer, but necessary for the specified or intended use, when known; * Requirements specified by Your Company; * Statutory and regulatory requirements applicable to products and services; * Contract or order requirements differing from those previously expressed. |  |  |
| Your Company ensures that contract or order requirements differing from those previously defined are resolved. The customer's requirements shall be confirmed by Your Company before acceptance, when the customer does not provide a documented statement of their requirements. In some situations, such as internet sales a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogs |  |  |
| 8.2.3.2 |  |  |
| Your Company shall **retain documented information**, as applicable:   * On results of the review; * On any requirements for the products and services. |  |  |
| 8.2.4 Changes to requirements for products and services |  |  |
| Your Company shall 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. |  |  |
| 8.3 Design and development of products and services |  |  |
| 8.3.1 General |  |  |
| Your Company has established, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services. |  |  |
| 8.3.2 Design and development planning |  |  |
| In determining the stages and controls for design and development Your Company has considered:   * The nature, duration and complexity of the design and development activities; * The required process stages, including applicable design and development reviews; * The required design and development verification and validation activities; * The responsibilities and authorities involved in the design and development process; * The internal and external resource needs for the design and development of products and services; * The need to control interfaces between persons involved in the design and development process; * The need for involvement of customers and users in the design and development process; * The requirements for subsequent provision of products and services; * The level of control expected for the design and development process by customers and other relevant interested parties; * The documented information needed to demonstrate that design and development compliance have been met. |  |  |
| 8.3.3 Design and development inputs |  |  |
| Your Company has determined the requirements essential for the specific types of products and services to be designed and developed. |  |  |
| Your Company has considered:   * Functional and performance requirements; * Information derived from previous similar design and development activities; * Statutory and regulatory requirements; * Standards or codes of practice that Your Company has committed to implement; * Potential consequences of failure due to the nature of the products and services. |  |  |
| Input shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. Your Company has **retained documented information** of design and development inputs. |  |  |
| 8.3.4 Design and development controls |  |  |
| Your Company has applied controls to the design and development process to ensure that:   * The results to be achieved are defined; * Reviews are conducted to evaluate the ability of the results of the design and development to meet requirements; * Verification activities conducted to ensure that the design and development efforts meet the input requirements, also; * Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; * Any necessary actions are taken on problems determined during the reviews, or verification of validation activities; * **Documented information of these activities is retained**. |  |  |
| Design and development reviews, verification validation have distinct purposes. They can be conducted separately or any combination as is suitable for the products and services of Your Company. |  |  |
| 8.3.5 Design and development outputs |  |  |
| Your Company has ensured that design and development outputs:   * Meet the input requirements; * Are adequate for the subsequent processes for the provision of products and services; * Included are reference monitoring measuring requirements, as appropriate, and acceptance criteria; * Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.   **Your** **Company has retained documented information on design and development outputs**. |  |  |
| 8.3.6 Design and development changes |  |  |
| Your Company has identified, reviewed and controlled 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. |  |  |
| Your Company has **retained documented information** on:   * Design and development changes; * The results of review; * The authorization of changes; * The actions taken to prevent adverse impacts |  |  |
| 8.4 Control of externally provided processes, products and service |  |  |
| 8.4.1 General |  |  |
| Your Company shall ensure that externally provided processes, products and services conform to requirements. |  |  |
| Your Company shall determine the controls to be applied to externally provided processes, products and services when:   * Products and services from external providers are intended for incorporation into Your Company's aim, products and services; * Products and services are provided directly to the customer by external providers on behalf of Your Company; * A process or part of a process provided by external provider as a result of a decision by Your Company; * Your Company shall determine and apply criteria for the evaluation, selection, monitoring of performance, and reevaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.   **Your Company shall retain documented information of these activities and any necessary actions arising from the evaluations.** |  |  |
| 8.4.2 Type and extent of control |  |  |
| Your Company shall ensure that externally provided processes, products and services do not adversely affect Your Company's ability to consistently deliver conforming products and services to its customers. |  |  |
| Your Company shall:   * Ensure that externally provided processes remain within the control of its quality management system; * Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting outputs; * Take into consideration:  1. The potential impact of the externally provided processes, products and services and Your Company's ability to consistently meet customer and applicable statutory and regulatory requirements; 2. The effectiveness of the controls applied by the external provider;  * Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. |  |  |
| 8.4.2 Information for external providers |  |  |
| Your Company shall ensure the adequacy of requirements prior to their communication to the external provider. |  |  |
| Your Company shall communicate to external providers its requirements for:   * The processes, products and services to be provided; * The approval of: * Products and services; * Methods, processes and equipment; * The release of products and services; * Competence, including any required qualification of persons; * The external providers interactions with Your Company; * Control and monitoring of external providers' performance to be applied by Your Company; * Verification or validation activities that Your Company, or its customer, intends to perform at the external providers' premises. |  |  |
| 8.5 Production and Service Provision |  |  |
| 8.5.1 Control of Production and Service Provision |  |  |
| Your Company shall implement production and service provision under control conditions. Control conditions shall include, as applicable:   * The ability 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;  * The availability and use of suitable monitoring measuring resources; * The implementation of monitoring and measurement activities at appropriate stages to verify criteria for control of processes or in/outputs, and acceptance criteria for products and services, have been met; * The use of suitable infrastructure and environment for the operation of processes; * The appointment of confident persons, including any required qualification; * The validation, and periodic reevaluation, of the ability to achieve plan results of the processes for production and so is provision, with the resulting output cannot be verified by subsequent monitoring or measurement; * The implementation of actions to prevent human error; * The implementation of release, delivery and post delivery activities. |  |  |
| 8.5.2 Identification and traceability |  |  |
| Your Company shall use suitable means to identify outputs when it is necessary to ensure the conformative products and services. |  |  |
| Your Company shall identify the status of outputs with respect to monitoring and measuring measurement requirements throughout production and service provision. |  |  |
| Your Company shall control the unique identification of the outputs when traceability is a requirement, and **shall retain the documented information** necessary to enable traceability. |  |  |
| 8.5.3 Property Belonging to Customers or External Providers |  |  |
| Your Company shall exercise care with property belonging to customers or external providers while it is under Your Company’s control or being used by Your Company. |  |  |
| Your Company shall identify, verify, protect, and safeguard customer's or external provider's property provided for use or incorporation with the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use. |  |  |
| Your Company shall report this to the customer or external provider and **retain documented information** on what has occurred. A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data. |  |  |
| 8.5.4 Preservation |  |  |
| Your Company shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Note, preservation can include identification handling, contamination control, packaging, storage transmission or transportation and protection. |  |  |
| 8.5.5 Post delivery activities |  |  |
| Your Company shall make requirements for post delivery activities associated with the products and services. In determining the extent of post delivery activities that are required, |  |  |
| Your Company shall consider:   * Statutory and regulatory requirements; * The potential undesired consequences associated with its products and services; * The nature, use and intended lifetime of its products and services; * Customer requirements; * Customer feedback.   Post delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal. |  |  |
| 8.5.6 Control changes |  |  |
| Your Company shall review and control changes for production or service provision to the extent necessary to ensure continuing conformity with requirements. |  |  |
| Your Company **shall retain documented information** describing the results of the review of change, the personal persons authorizing the change, and any necessary actions arising from the review. |  |  |
| 8.6 Release of Products and Services |  |  |
| Your Company shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to their customers shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. |  |  |
| Your Company shall **retain documented information** on the release of products and services. The documented information shall include:   * Evidence of conformity with the acceptance criteria; * Traceability to the person/persons authorizing the release. |  |  |
| 8.7 Control of Nonconforming Outputs |  |  |
| 8.7.1 |  |  |
| Your Company shall ensure that outputs that do not conform to clients are identified as control and control to prevent their unintended use of delivery. |  |  |
| Your Company shall take appropriate action based on the nature of the nonconformity and its effects on the conformative products and services. This shall also apply to conforming products and services detected after delivery of products, during or after the provision of services. |  |  |
| Your Company shall deal with nonconforming outputs in one or more of the following ways:   * Corrections; * Segregation, containment, return or suspension of the provision or products and services; * Informing the customer; * Obtain authorization for acceptance under concession.   Conforming to the requirements shall be reviewed, shall be verified when nonconforming outputs are corrected. |  |  |
| 8.7.1 |  |  |
| Your Company shall **retrain documented information** that:   * Describes to low confirmatory; * Describes the actions taken; * Describes any concessions of time; * Identifies the authority deciding the action in respect of the conformity. |  |  |
| 9 Performance Evaluation |  |  |
| 9.1 Monitoring, measurement and evaluation |  |  |
| 9.1.1 General |  |  |
| Your Company determines:   * what needs to be monitored and measured; * the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; * when the monitoring and measuring are performed; * when the results from monitoring and measurement are analysed and evaluated. |  |  |
| Your Company evaluates the performance and the effectiveness of the quality management system. Your Company **retains appropriate documented information** as evidence of the results. |  |  |
| 9.1.2 Customer Satisfaction |  |  |
| Your Company monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. |  |  |
| Your Company determines the methods for obtaining, monitoring and reviewing this information. Examples of monitoring customer perceptions can include but not limited to customer surveys, customer feedback on delivered products and services, meetings with customers, market share analysis, compliments, warranty claims and dealer reports |  |  |
| 9.1.3 Analysis and evaluation |  |  |
| Your Company analyses and evaluates appropriate data and information arising from monitoring and measurement. The results of analysis are used to evaluate;   * conformity of products and services; * the degree of customer satisfaction; * the performance and effectiveness of the quality management system; * if planning has been implemented effectively; * the effectiveness of actions taken to address risks and opportunities; * the performance of external providers; * the need for improvements to the quality management system. |  |  |
| Methods to analyse data can include statistical techniques such as but not limited to sampling plans, acceptability limits, standard deviations, etc. |  |  |
| 9.2 Internal Audits |  |  |
| 9.2.1 |  |  |
| Your Company conducts internal audits at planned intervals to provide information on whether the quality management system:   * Conforms to:   1. Your Company's own requirements for its quality management system;   2. the requirements of this standard; * Is effectively implemented and maintained. |  |  |
| 9.2.1 |  |  |
| Your Company:   * plans, establishes, implements and maintains an audit program, including the frequency, methods, responsibilities, planning, requirements and reporting which shall take into consideration the importance of the process concerned, changes affecting Your Company, and the results of previous orders; * defines the order criteria and scope for each order; * selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process; * ensures that results of the audits are reported to the relevant management; * takes appropriate correction and corrective actions without undue delay; * **retains documented information** as evidence of the implementation of the audit program and the audit results. |  |  |
| 9.3 Management Reviews |  |  |
| 9.3.1 General |  |  |
| Top management reviews Your Company's quality management system at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of Your Company. |  |  |
| 9.3.2 Management review inputs |  |  |
| The management reviews are planned and carried out taking into consideration:   * the status of actions from previous management reviews; * changes in external and internal issues that are relevant to the quality management system; * 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 in conformative products and services;     4. non-conformities and corrective actions;     5. monitoring and measurement results;     6. audit results;     7. the performance of external providers; * the adequacy of resources; * the effectiveness of actions taken to address risks and opportunities [see 6.1] * opportunities for improvement. |  |  |
| 9.3.3 Management review outputs |  |  |
| The outputs of the management review include decisions and actions related to:   * opportunities for improvement; * any need for changes to the quality managed system; * resource needs.   Your Company **retains documented information** as evidence of the results of management reviews. |  |  |
| 10 Improvement |  |  |
| 10.1 General |  |  |
| Your Company determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. |  |  |
| These include:   * improving products and services to meet requirements as well as to address future needs and expectations; * correcting, preventing, or reducing undesired effects; * improving the performance and effectiveness of the quality management system.   Examples of improvement can include but not limited to correction, corrective action, continual improvement, breakthrough change, innovation, and reorganization. |  |  |
| 10.2 Nonconformity and corrective action |  |  |
| 10.2.1 |  |  |
| When a nonconformity occurs, including any arising from complaints, Your Company will:   * react to the nonconformity and, as applicable:   + 1. take action to control and correct it;     2. deal with the consequences; * evaluate the need for action to eliminate the cause[s] of the nonconformity, in order that it does not recur or occur or swear, by:   + 1. reviewing and analyzing the nonconformity;     2. determining the causes of the nonconformity;     3. determining if similar nonconformities exist, or could potentially occur; * implement any action noted; * review the effectiveness of any corrective action taken; * update risks and opportunities determined during planning, if necessary; * make changes to the quality management system, if necessary.   Corrective actions are appropriate to the effects of the nonconformities encountered. |  |  |
| 10.2.2 |  |  |
| Your Company **retains documented information** as evidence of the:   * nature of the nonconformities and any subsequent actions taken; * results of any corrective action |  |  |
| 10.3 Continual Improvement |  |  |
| Your Company continually improves the suitability, adequacy, and effectiveness of the quality management system. |  |  |
| Your Company considers the results of analysis and evaluation, and the outputs from the management review, to determine if there are needs or opportunities that shall be addressed as part of the continual improvement. |  |  |
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