5.1.2	Customer Focus	37	Describe how Top management ensure focus maintained on consistently providing products and services that enhance customer satisfaction. This could be how you know exactly what the customer wants and documenting this from initial enquiry, through to commissioning and delivery paper work. E.g. Action is taken when product and service conformity and on-time delivery performance is not achieved e.g. ownership, containment, root cause, corrective action, continual improvement.
5.2.1	Establishing the Quality Policy	38	Describe Top management's provision for establishing the quality policy including its appropriateness and alignment to the context of the organization (see 4.1), e.g. purpose, strategic direction, mission, vision, ethical principles, business reputation, core values, business/functional policies and codes of conduct etc.
5.2.1	Establishing the Quality Policy	39	Describe Top management's provision for establishing a framework for setting quality objectives (see 6.2), e.g. business planning, core themes, strategic enablers, key performance indicators (KPIs), milestones, and resources.
5.2.1	Establishing the Quality Policy	40	Describe Top management's provision for their commitment to satisfy applicable internal/external requirements e.g. industry, business, customer, statutory, regulatory and other interested parties (see 4.2).
5.2.1	Establishing the Quality Policy	41	Describe Top management's provision for their commitment towards continuous improvement of the QMS e.g. business performance, process maturity, process effectiveness, customer expectations, investment, organizational growth and scope application.
5.2.2	Communicating the Quality Policy	42	Demonstrate where the quality policy is available as documented information.
5.2.2	Communicating the Quality Policy	43	Determine how the quality policy is communicated within the organization. Interviews with staff will likely show how this is understood and applied. Awareness, understanding and application across the organization (see 7.3 and 7.4) e.g. communication methods (meetings, briefs, e-mail, websites), responding to feedback, providing interpretation, translation into other languages (as required), timing and frequency.
5.2.2	Communicating the Quality Policy	44	Determine how the quality policy is communicated externally, this can be as simple as posting it in reception on your website. Availability across the organization and methods used to deploy e.g. hard copies displayed in prominent places, electronic copies via intranet/internet sites, identification and distribution to relevant interested parties.
5.3	Roles, Responsibilities & Authorities	45	Examples might include an organization chart, defined job roles prior to recruitment, allocated job descriptions to personnel and linking these activities to the processes within your business.
5.3	Roles, Responsibilities & Authorities	46	Describe how Top management assigns responsibility and authority to maintain QMS conformity. Has your organization delegated responsibility and authority to a Quality Manager, or the duties assigned to Department Heads?
5.3	Roles, Responsibilities & Authorities	47	Describe how Top management assigns responsibility and authority for monitoring and reporting on the operation and performance of the QMS, via audits and inspections, business meetings, and KPI reviews, etc. Assignment of relevant roles, responsibilities and authorities across the organization e.g. top management, functional leaders, heads of departments, process owners, lead process users, end users etc. relating to: 1. Conformance of the QMS & ISO 9001 (4.3); 2. Delivery of process output results (4.4.1); 3. Reporting of QMS performance and improvement opportunities (9.3); 4. Promoting customer focus (5.1.2); 5. Maintaining QMS integrity when change occurs (6.3).
5.3	Roles, Responsibilities & Authorities	48	Describe how the performance of the QMS, opportunities for improvement and the need for change or innovation are reported to Top management.
5.3	Roles, Responsibilities & Authorities	49	Describe how customer focus is promoted within your organization. This will link to Clause 5.1.2 – Questions 35 to 37.
5.3	Roles, Responsibilities & Authorities	50	Describe how Top management have assigned responsibility and authority for preserving the integrity of your organization's QMS during changes.
6.1.1	Actions to Address Risks & Opportunities	51	Describe the organizational arrangements for addressing the identified risks and opportunities, including those that have an impact on the QMS achieving its intended results e.g. conformity to requirements, realizing objectives, meeting performance targets.
6.1.1	Actions to Address Risks & Opportunities	52	Describe the organizational arrangements for addressing the identified risks and opportunities, including those that have an impact on enhancing the desirable effects e.g. developing opportunities, creating new possibilities, exploring new markets, expanding the customer base, organization growth.
6.1.1	Actions to Address Risks & Opportunities	53	Describe the organizational arrangements for addressing the identified risks and opportunities, including those that have an impact on preventing or reducing undesired effects e.g. proactive risk management, focusing on risk reduction, taking preventive measures.
6.1.1	Actions to Address Risks & Opportunities	54	Describe the organizational arrangements for addressing the identified risks and opportunities, including those that have an impact on Achieving improvement e.g. meeting targets, removing non-value added activity (waste), positive performance trends.
6.1.2	Actions to Address Risks & Opportunities	55	Describe the organizational arrangements for planning actions to address the identified risks and opportunities to ensure that appropriate process controls are in place e.g. ownership, documented information, instructions, methods, verification activity, process monitoring, performance measures and trends, training and competency.
6.1.2	Actions to Address Risks & Opportunities	56	Describe the organizational arrangements for integrating and implementing actions into the QMS e.g. capture of lessons learned, sharing good practice, process reviews, process updates, change control and communication.
6.1.3	Actions to Address Risks & Opportunities	57	Describe the organizational arrangements for determining, analysing and evaluating opportunities separately from risks (e.g. the F0611-02 Opportunity Evaluation Form and the Opportunity entries in the F0611-01 Risk & Opportunity Register), and for planning actions that are appropriate to the organization's context and support the achievement of desired results, e.g. adopting new practices, launching new products or services, creating new partnerships, leveraging emerging technologies or implementing initiatives.
6.1.2	Actions to Address Risks & Opportunities	58	Describe the organizational arrangements for managing risks and opportunities taking into account: 1. Level of activity proportionate to the size and complexity of the organization and the impact on the conformity of products and services; 2. Application of risk management techniques including; risk management plan, risk identification, likelihood/impact of occurrence, severity of outcome (e.g. high, medium, low), risk ownership, risk treatment, residual risk, continual monitoring etc.
6.2.1	Quality Objectives	59	Describe the organizational arrangements for setting quality objectives at various levels across the organization including: 1. Objectives established within the relevant functions (Engineering, Purchasing, Finance, Human Resources, Quality, IT etc.), linked to the respective functional strategy, e.g. functional direction, process improvement, milestones etc.; 2. Objectives established within relevant processes that could include; direction defined by the process owner relating to the aims of the process, e.g. what the process is trying to achieve, resources needed, timescales etc.; 3. Objectives established and suitably cascaded at various levels across the organization structure e.g. top management, middle management, supervisors, departments, projects, groups, individuals.
6.2.1	Quality Objectives	60	Determine whether the quality objectives are consistent with the quality policy (see 5.2.1) to ensure that they underpin the strategic direction of the organization, support the needs and expectations of interested parties and enhance customer satisfaction.
6.2.1	Quality Objectives	61	Determine whether the quality objectives are measureable: Specific and measurable in order to give clear direction as to what is required and the expected outcome, often referred to as SMART (Specific, Measurable, Attainable, Realistic and Time-bound) objectives.
6.2.1	Quality Objectives	62	Determine whether the quality objectives take account of applicable requirements and are they aligned to applicable requirements e.g. those defined by the organization, customer or regulator and relevant to the conformity of products and services.
6.2.1	Quality Objectives	63	Determine whether the quality objectives are relevant to the conformity of products and services and whether they enhance customer satisfaction.
6.2.1	Quality Objectives	64	Determine whether the quality objectives are monitored using suitable means to ensure that the objectives are being met e.g. Business Plan Deployment (BPD) charts, dash boards, matrices, reports, progress charts, traffic light charts, management review. The use of indicators needs to be audited in detail; are objectives based on sound information? Are indicators really related to the corresponding objectives? Are statistical tools needed to define and to monitor objectives? If the indicators reach the expected values, how can your organization assure that the objective has been achieved?
6.2.1	Quality Objectives	65	Determine whether the quality objectives are communicated at the relevant levels within the organization to ensure that teams and individuals are aware of their importance and contribution.
6.2.1	Quality Objectives	66	Determine whether the quality objectives are updated accordingly to demonstrate progress and to take account of changing circumstances that could result in new, expanded, amended, cancelled objectives etc.
6.2.1	Quality Objectives	67	Determine whether the quality objectives are available as documented information.
6.2.2	Objectives & Planning to Achieve Them	68	Describe the organizational arrangements for determining what will be done e.g. clearly established objectives across the organization at various levels (functional, process, department, and team, individual) that are measurable - see 6.2.1.
6.2.2	Objectives & Planning to Achieve Them	69	Describe the organizational arrangements for determining what resources required to deliver the objectives e.g. number and competency of people, adequate infrastructure, suitable working environment, organizational knowledge, investment, budgets, and external provision.
6.2.2	Objectives & Planning to Achieve Them	70	Describe the organizational arrangements for determining responsibility for achieving objectives at the various levels within the organization e.g. top management, functional leadership, department leadership, process owners, teams and individuals.
6.2.2	Objectives & Planning to Achieve Them	71	Describe the organizational arrangements for determining the timescales for achieving objectives e.g. stepped achievement (weekly, monthly, quarterly), specific milestones (defined dates or periods), or annual achievement.
6.2.2	Objectives & Planning to Achieve Them	72	Describe the organizational arrangements for determining the methods used to evaluate the results e.g. periodic comparison of performance against established targets or expectations during management review, functional reviews, process councils, departmental reviews, personal development reviews (appraisals), and team meetings.
6.3	Planning for Change	73	Describe your organization's approach to ensure that changes to the QMS are planned and implemented in a controlled manner.
6.3	Planning for Change	74	The reason for the change; e.g. context of the organization (see 4.1), needs of interested parties (see 4.2), customer feedback, complaints analysis, audit results, performance trends, risk reduction or realizing an opportunity (see 6.1), continual improvement, organization growth, launch of new products, or organizational restructuring etc.
6.3	Planning for Change	75	Describe how your organization applies risk and opportunity management techniques to changes to the QMS that are planned to help better manage the change. Assessing the purpose of the change(s) and potential impact using a risk based thinking approach to ensure the integrity of the QMS is maintained i.e. focus on priorities, avoid disruption, ensure business continuity, maintain product reliability, protect the customer, maintain capability, continue to meet internal and external requirements etc.
6.3	Planning for Change	76	Describe how your organization considers the resources required to enable the change such as people, knowledge acquisition, infrastructure, environment, budget, trials/tests, ongoing monitoring, or structured reviews etc.
6.3	Planning for Change	77	Describe how your organization determines the responsibility and authority for the change e.g. process owner, lead process users, end users etc., including the necessary communication, training and ongoing review to ensure the change is effective.
7.1.1	General	78	Check that a budget has been allocated to the QMS and your organization has identified all types of resources required and that it has taken action to ensure that those resources will be available when needed.
7.1.1	General	79	Describe how the capabilities and constraints on internal resources are considered, and how the needs of external providers are considered.
7.1.1	General	80	Your organization has to identify which resources it needs to make available in order to ensure the effective operation of the QMS. Resources e.g. raw materials, infrastructure, finance, personnel and IT, all of which can be either internally or externally provided.

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Ref No.	Clause Title	Q-No	Guidance & Suggestions
9.1.1	General	248	Describe the organizational arrangements for using Statistical process control (SPC) including run charts, histograms, control charts, Pareto diagrams, scatter diagrams, cause and effect (fishbone) diagrams, glyph/radar charts, experiments are examples of determining intervals of measurement frequency.
9.1.1	General	249	Describe the organizational arrangements for determining when measurements are evaluated and analysed. Stimulus for monitoring and measurement includes data from various indexes such as: project earned value, including cost performance index (CPI) and schedule performance index (SPI)
9.1.1	General	250	Describe the organizational arrangements for performance governance, e.g. management review, process reviews/councils, performance reports, score cards and dashboards.
9.1.1	General	251	What documented information demonstrates that monitoring and measurement activities have been implemented in accordance with determined requirements?
9.1.2	Customer Satisfaction	252	Describe the organizational arrangements for determining the methods used for obtaining, monitoring and reviewing customer perception, e.g. customer surveys and questionnaires. Surveys can relate to all customers or a representative sample and the frequency may vary according to the relationship. Customer feedback might relate to delivered products and services, conformity, on time delivery, report cards, satisfaction indicators, and compliments.
9.1.2	Customer Satisfaction	253	Customer communication includes: face to face meetings, telephone calls, use of installation/service personnel, day to day enquires, use of social media (websites, message boards, on-line help), reports from dealers, distributors, integrators. Complaint profile including rejections, returns, warranty claims, invoice queries, corrective action requests, market share analysis and evaluation of repeat business.
9.1.3	Analysis & Evaluation	254	Describe the organizational arrangements for analysing appropriate data arising from monitoring and measurement (see 9.1.1) in order to evaluate QMS and process performance: e.g. achievement of quality objectives, process performance indicators, target setting, audit results (conformity /nonconformity, effectiveness) and trends.
9.1.3a	Analysis & Evaluation	255	Operational performance, e.g. product conformity, production yield, right first time, parts per million (PPM), defects per unit (DPU), product characteristics, process parameters, process capability, identification of waste, on time delivery, queuing times, resolution of customer issues, service availability, and in-service reliability.
9.1.3b	Analysis & Evaluation	256	Customer performance, e.g. survey results, satisfaction indicators/ratings, compliments, complaint profile, returns/rejections, warranty claims and invoice queries.
9.1.3c	Analysis & Evaluation	257	QMS and process performance e.g. achievement of quality objectives, process performance indicators, target setting, audit results (conformity/nonconformity, effectiveness) and trends.
9.1.3d	Analysis & Evaluation	258	Consider if planning has been implemented effectively, e.g. actions to address risks and opportunities, achievement of quality objectives, planning of changes, and operational planning.
9.1.3e/f	Analysis & Evaluation	259	Describe the effectiveness of actions taken to address risks and opportunities, e.g. risk assessment, risk treatment, residual risk values, and performance trends, adoption of new practices, launching new products and winning new customers.
9.1.3g	Analysis & Evaluation	260	Methods for evaluating external provider performance include, e.g. product conformity, on time delivery, approval ratings, returns/rejections and invoice queries.
9.1.3h	Analysis & Evaluation	261	Describe the use of documented output from analysis and evaluation activities, e.g. trend analysis and reports as an input to management review (see 9.3.2) to enable the organization to determine the performance and effectiveness of the QMS and identify improvements. Is the analysis of the data can be undertaken using statistical techniques to help break down the information and present it in a format that allows a determination to be made of whether actions are needed?
9.2.1	Internal Audit - General	262	Describe what your organization's arrangements for conducting internal audits at planned intervals to demonstrate that the QMS conforms to: 1. Your own requirements, e.g. policies, processes, procedures, instructions, specifications; 2. Customer requirements, e.g. flowed down by contract; 3. Statutory and Regulatory requirements; 4. Applicable external standards (including ISO 9001).
9.2.1	Internal Audit - General	264	Define your organization's approach to knowing how well the QMS has been effectively implemented and maintained for example by: 1. Obtaining audit results; 2. Reporting audit performance; 3. Monitoring trends, e.g. process strengths and weakness, repeat audit findings, acknowledged improvement.
9.2.2	Internal Audit Programme	265	Does your organization publish its audit programme, or a number of audit programs dependent upon the size and complexity of your business, including previous audit results, the identification (title, scope, criteria) and frequency of each audit, e.g. monthly, quarterly, or annually?
9.2.2	Internal Audit Programme	266	Definition of the criteria, (policy, process, procedure, requirements) and scope (extent, boundaries, physical location, product line, facility, department, activities, duration) for each identified audit.
9.2.2	Internal Audit Programme	267	Auditor resources including training/qualification and selection of auditors to ensure independence of the area/process being audited. The collection of audit evidence and reporting of audit findings including correct grading of findings (conformity, nonconformity, strengths, and opportunities for improvement).
9.2.2	Internal Audit Programme	268	Describe the organizational arrangements for the routine reporting of audit results to the relevant management (circulation of audit report, closing meeting and audit performance metrics); including an input to Management Review (see 9.3.2).
9.2.2	Internal Audit Programme	269	Describe the organizational arrangements for the timely undertaking of corrections (fix the issue) and corrective actions (prevent recurrence) by the organization. Follow up by the auditor to ensure effective and timely implementation of correction and corrective action.
9.2.2	Internal Audit Programme	270	Retention of documented information to show that that the audit program has been effectively implemented (audit program, audit plans, audit reports, questionnaires, audit evidence, corrective action, audit close out, auditor qualification, audit performance metrics).
9.3.1	Management Review - General	271	What are Top management's arrangements for reviewing the QMS at planned intervals to ensure continuing: suitability (fit for purpose), adequacy (meets the needs of the organization) and its effectiveness (achieves intended results).
9.3.2a	Management Review - Inputs	272	What is the current status of actions (open/closed) from previous meeting(s), what is the age profile of open actions, e.g. 3 months, 6 months, 12 months, greater than 1 year?
9.3.2b/c	Management Review - Inputs	273	Changes arising from monitoring internal/external issues that are relevant to the QMS (see 4.1) Identification and evaluation of changes to internal/external requirements, e.g. policies, processes, procedures, methods, instructions, contracts, regulation, legislation, that impact the QMS.
9.3.2d4	Management Review - Inputs	274	QMS performance and effectiveness includes the levels of customer satisfaction (see 9.1.2) and feedback from other interested parties, e.g. report cards, indicators, ratings, complaints, compliments and media reports.
9.3.2d5	Management Review - Inputs	275	Ensures that the achievement of quality objectives (see 6.2), includes the status of planned, versus actual achieved.
9.3.2d6	Management Review - Inputs	276	Organization and external provider process performance and product conformity (see 4.4, 8.4 and 8.6), e.g. dashboards, scorecards, performance indicators, performance trends, right first time, on time delivery, escapes to the customer, complaint profile, returns and rejections.
9.3.2d1	Management Review - Inputs	277	Nonconformity and corrective action (see 10.2) e.g. Pareto of nonconformity by type, process, area, root cause etc., read across to other parts of the organization or to external parties, update of risks (see 6.1 and 8.1) and the status of corrective action implementation.
9.3.2d2	Management Review - Outputs	278	QMS performance and effectiveness includes data relating to customer satisfaction (see 9.1.2) and feedback from other interested parties, e.g. report cards, indicators, ratings, complaints, compliments, media reports, and the achievement of quality objectives (see 6.2), including status of planned versus actual achievement.
9.3.2d3	Management Review - Outputs	279	Audit results (see 9.2), e.g. achievement of the audit program(s), areas of good practice, nonconformity profile (number, type, process, area, significance), status of corrective action, audit close out and external audit findings.
9.3.2d7	Management Review - Outputs	280	Organization and external provider process performance and product conformity (see 4.4, 8.4 and 8.6), e.g. dashboards, scorecards, performance indicators, performance trends, right first time, on time delivery, escapes to the customer, complaint profile, returns or rejections.
9.3.2f	Management Review - Inputs	281	Adequacy of internal resources and external providers (see 7.1) including people (number, roles, competency etc.), infrastructure (buildings, equipment, systems, transport etc.), working environment (physical and human factors, monitoring and measuring equipment (availability, fit for purpose, maintained).
9.3.2g/h	Management Review - Inputs	282	Effectiveness of actions taken to address risks and opportunities (see 6.1), e.g. risk profile, risk register(s), status of open/closed actions, ageing profile of open actions, evaluation of effectiveness (enhance desirable effects, prevent, reduce undesired effects and demonstrated improvement).
9.3.2e	Management Review - Inputs	283	Identification of opportunities for improvement (see 10.1), corrective action, good practice, best practice, innovation, lessons learned etc., including read across the organization and to external providers.
9.3.3	Management Review - Outputs	284	Opportunities for improvement (see 10.1) e.g. read across and implementation of corrective action, good practice, best practice, innovation and lessons learned, etc.
9.3.3	Management Review - Outputs	285	Changes to the QMS (see 6.3), e.g. policies, processes, procedures, methods, instructions. Identified risks (see 6.1 and 8.1), e.g. adding new risks at an organization or operational level to the appropriate register(s) and the assignment of responsibility and treatment.
9.3.3	Management Review - Outputs	286	Resource needs (see 7.1), e.g. people (number, roles, training), infrastructure (buildings, equipment, systems, transport), working environment (physical and human factors), monitoring and measuring equipment (availability, fit for purpose, maintained).
9.3.3	Management Review - Outputs	287	Documented evidence of the review, e.g. attendance, agenda, presentations, meeting minutes, actions (list, owners, timescale), reports. Retention of documented information of the review and communication of the relevant content across the organization (see 7.4).
10.1	General	288	Describe the organizational arrangements for identifying opportunities for improvement and taking action in order to enhance customer satisfaction e.g. using satisfaction indicators/ratings, complaints profile, returns/rejections and warranty claims (see 9.1.2).
10.1	General	289	Describe the organizational arrangements for meeting customer requirements and expectations e.g. understanding contractual arrangements and implied customer expectations. Focus on improving products and services, including future needs and expectations, e.g. investment in latest technology and innovation, improving reliability, improving yield, reducing cost, and improving on-time delivery.
10.1	General	290	Describe the organizational arrangements for correcting, preventing and reducing undesired effects, e.g. investigating root cause, preventing escapes to the customer, acting on customer feedback and/or in service reports.
10.1	General	291	Describe the organizational arrangements for improving the performance and effectiveness of its QMS, e.g. acting on process performance results, understanding audit findings, reducing waste, process re-engineering, structural re-organization, and promoting breakthrough projects.
10.2.1	Nonconformity & Corrective Action	292	Describe the organizational arrangements for reacting to nonconformities when they arise from sources such as nonconforming product (identified during manufacture or post-delivery), customer complaints, audit findings, warranty claims, etc.
10.2.1	Nonconformity & Corrective Action	293	Describe the organizational arrangements for taking action to control and correct the nonconformity, e.g. understanding the problem, applying immediate containment (protect the customer), undertaking correction and corrective action.
10.2.1	Nonconformity & Corrective Action	294	Describe the organizational arrangements for evaluating the need to take action to eliminate the cause of the nonconformity to ensure it doesn't exist elsewhere and to prevent recurrence by reviewing and analyzing the nonconformity e.g. describing the problem (who, what, when, where, how, how many), assigning a problem owner, launching an investigation, collecting information, engagement with others with product/process knowledge
10.2.1	Nonconformity & Corrective Action	295	Describe the organizational arrangements for using appropriate methodologies, e.g. root cause analysis, 3 W, 5 Whys, Ishikawa (cause and effect diagram), Pareto charts, process flow diagram, 8 disciplines of problem solving (8d), 9 steps to problem solving (9s), Failure Mode and Effect Analysis (FMEA) etc. to determine the cause(s) of the nonconformity (including those related to Human Factors) and extent of the action(s) needed, based upon the potential effect of the nonconformity.
10.2.1	Nonconformity & Corrective Action	296	Describe the organizational arrangements for determining if similar nonconformities exist or could occur elsewhere e.g. communication within and outside the organization (as appropriate), verification and quarantine (if required) of other products that could potentially be impacted (work in progress, product held by external providers, stock held in storage, product already delivered to the customer)
10.2.1	Nonconformity & Corrective Action	297	Describe the organizational arrangements for implementing and monitoring identified action(s) through the use of action plan(s), owner(s), resources, tasks, timescales, management review etc. to ensure timely corrective action is taken, and any external provider(s) where necessary and that further action is taken when timely and effective corrective action is not achieved.
10.2.1	Nonconformity & Corrective Action	298	Describe the organizational arrangements for reviewing the effectiveness of corrective action(s) taken, e.g. observing the performance of the process, reviewing documented information, conducting compliance checks or audits to ensure the root cause was addressed and that no issues were caused by the action.
10.2.1	Nonconformity & Corrective Action	299	Describe the organizational arrangements for conducting a follow up to ensure that planning is updated if necessary (see 6.1) to capture any identified risks and opportunities that were not previously considered.
10.2.1	Nonconformity & Corrective Action	300	Describe the organizational arrangements for conducting a follow up to ensure changes are incorporated into the QMS if necessary, (process documents, procedures, work instructions, control plan, service plan, drawings, resources etc.)
10.2.1	Nonconformity & Corrective Action	301	Describe the organizational arrangements for ensuring that correction actions are appropriate to the effects of the nonconformities encountered.
10.2.2	Nonconformity & Corrective Action	302	Describe the organizational arrangements for retaining documented information, which evidences: 1. Nature of the nonconformities, e.g. source, type, quantity, frequency, severity; 2. Action(s) taken, e.g. corrective action documents, action trackers, management review outputs, lessons learned, risk registers, on-line systems; 3. Results of corrective action e.g. open versus closed, achievement of milestones, performance measures (time to close and problem recurrence, and cost.

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