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1.	**4 Context of the organization**		
2.	**4.1 Understanding the organization and its context**		
3.	The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.		
4.	The organization shall monitor and review information about these external and internal issues.		
5.	NOTE 1 Issues can include positive and negative factors or conditions for consideration.		
6.	NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.		
7.	NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.		
8.	**4.2 Understanding the needs and expectations of interested parties**		
9.	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:		
10.	a) the interested parties that are relevant to the quality management system;		
11.	b) the requirements of these interested parties that are relevant to the quality management system.		
12.	The organization shall monitor and review information about these interested parties and their relevant requirements.		
13.	**4.3 Determining the scope of the quality management system**		
14.	The organization shall determine the boundaries and applicability of the quality management system to establish its scope.		

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15.	When determining this scope, the organization shall consider:		
16.	a) the external and internal issues referred to in 4.1;		
17.	b) the requirements of relevant interested parties referred to in 4.2;		
18.	c) the products and services of the organization.		
19.	The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.		
20.	The scope of the organization's quality management system shall be available and be maintained as documented information.		
21.	The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.		
22.	Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.		
23.	**4.4 Quality management system and its processes**		
24.	**4.4.1** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Std.		
25.	***The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.***		
26.	The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:		
27.	a) determine the inputs required and the outputs expected from these processes;		
28.	b) determine the sequence and interaction of these processes;		
29.	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;		

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30.	d) determine the resources needed for these processes and ensure their availability;		
31.	e) assign the responsibilities and authorities for these processes;		
32.	f) address the risks and opportunities as determined in accordance with the requirements of 6.1;		
33.	g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;		
34.	h) improve the processes and the quality management system.		
35.	**4.4.2** To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes;		
36.	b) retain documented information to have confidence that the processes are being carried out as planned.		
37.	***The organization shall establish and maintain documented information that includes:*** ***– a general description of relevant interested parties (see 4.2 a);***		
38.	***– the scope of the quality management system, including boundaries and applicability (see 4.3);***		
39.	***– a description of the processes needed for the quality management system and their application throughout the organization;***		
40.	***– the sequence and interaction of these processes;***		
41.	***– assignment of the responsibilities and authorities for these processes.***		
42.	***NOTE: The above description of the quality management system can be compiled into a single source of documented information and referred to as a quality manual.***		
43.	**5 Leadership**		
44.	**5.1 Leadership and commitment**		

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45.	**5.1.1 General**		
46.	Top management shall demonstrate leadership and commitment with respect to the quality management system by:		
47.	a) taking accountability for the effectiveness of the quality management system;		
48.	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;		
49.	c) ensuring the integration of the quality management system requirements into the organization's business processes;		
50.	d) promoting the use of the process approach and risk-based thinking;		
51.	e) ensuring that the resources needed for the quality management system are available;		
52.	f) communicating the importance of effective quality management and of conforming to the quality management system requirements;		
53.	g) ensuring that the quality management system achieves its intended results;		
54.	h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;		
55.	i) promoting improvement;		
56.	j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.		
57.	NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.		
58.	**5.1.2 Customer focus**		
59.	Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:		

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60.	a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;		
61.	b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;		
62.	c) the focus on enhancing customer satisfaction is maintained.		
63.	d) ***product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.***		
64.	**5.2 Policy**		
65.	**5.2.1 Establishing the quality policy**		
66.	Top management shall establish, implement and maintain a quality policy that:		
67.	a) is appropriate to the purpose and context of the organization and supports its strategic direction;		
68.	b) provides a framework for setting quality objectives;		
69.	c) includes a commitment to satisfy applicable requirements;		
70.	d) includes a commitment to continual improvement of the quality management system.		
71.	**5.2.2 Communicating the quality policy**		
72.	The quality policy shall:		
73.	a) be available and be maintained as documented information;		
74.	b) be communicated, understood and applied within the organization;		
75.	c) be available to relevant interested parties, as appropriate.		
76.	**5.3 Organizational roles, responsibilities and authorities**		
77.	Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.		

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78.	Top management shall assign the responsibility and authority for:		
79.	a) ensuring that the quality management system conforms to the requirements of this International Standard;		
80.	b) ensuring that the processes are delivering their intended outputs;		
81.	c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;		
82.	d) ensuring the promotion of customer focus throughout the organization;		
83.	e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.		
84.	***Top management shall appoint a specific member of the organization's management, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements.***		
85.	***The management representative shall have the organizational freedom and unrestricted access to top management to resolve quality management issues.***		
86.	***NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.***		
87.	**6 Planning**		
88.	**6.1 Actions to address risks and opportunities**		
89.	**6.1.1** When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:		
90.	a) give assurance that the quality management system can achieve its intended result(s);		
91.	b) enhance desirable effects;		
92.	c) prevent, or reduce, undesired effects;		

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93.	d) achieve improvement.		
94.	**6.1.2** The organization shall plan:		
95.	a) actions to address these risks and opportunities;		
96.	b) how to:		
97.	1) integrate and implement the actions into its quality management system processes (see 4.4);		
98.	2) evaluate the effectiveness of these actions.		
99.	Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.		
100.	NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.		
101.	NOTE 2 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 the organization's or its customers' needs.		
102.	**6.2 Quality objectives and planning to achieve them**		
103.	**6.2.1** The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.		
104.	The quality objectives shall:		
105.	a) be consistent with the quality policy;		
106.	b) be measurable;		
107.	c) take into account applicable requirements;		
108.	d) be relevant to conformity of products and services and to enhancement of customer satisfaction;		
109.	e) be monitored;		

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110.	f) be communicated;		
111.	g) be updated as appropriate.		
112.	The organization shall maintain documented information on the quality objectives.		
113.	**6.2.2** When planning how to achieve its quality objectives, the organization shall determine: a) what will be done;		
114.	b) what resources will be required;		
115.	c) who will be responsible;		
116.	d) when it will be completed;		
117.	e) how the results will be evaluated.		
118.	**6.3 Planning of changes**		
119.	When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).		
120.	The organization shall consider:		
121.	a) the purpose of the changes and their potential consequences;		
122.	b) the integrity of the quality management system;		
123.	c) the availability of resources;		
124.	d) the allocation or reallocation of responsibilities and authorities.		
125.	**7 Support**		
126.	**7.1 Resources**		
127.	**7.1.1 General**		
128.	The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.		

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129.	The organization shall consider:		
130.	a) the capabilities of, and constraints on, existing internal resources;		
131.	b) what needs to be obtained from external providers.		
132.	**7.1.2 People**		
133.	The organization 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.		
134.	**7.1.3 Infrastructure**		
135.	The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.		
136.	NOTE Infrastructure can include:		
137.	a) buildings and associated utilities;		
138.	b) equipment, including hardware and software;		
139.	c) transportation resources;		
140.	d) information and communication technology.		
141.	**7.1.4 Environment for the operation of processes**		
142.	The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.		
143.	NOTE A suitable environment can be a combination of human and physical factors, such as:		
144.	a) social (e.g. non-discriminatory, calm, non-confrontational);		
145.	b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);		
146.	c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).		
147.	These factors can differ substantially depending on the products and services provided.		

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148.	**7.1.5 Monitoring and measuring resources**		
149.	**7.1.5.1 General**		
150.	The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.		
151.	The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken;		
152.	b) are maintained to ensure their continuing fitness for their purpose.		
153.	The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.		
154.	**7.1.5.2 Measurement traceability**		
155.	When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:		
156.	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;		
157.	b) identified in order to determine their status;		
158.	c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.		
159.	***The organization shall establish, implement, and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.***		
160.	***The organization shall maintain a register of the monitoring and measuring equipment.***		

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161.	***The register shall include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.***		
162.	***NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.***		
163.	***Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).***		
164.	The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose,		
165.	and shall take appropriate action as necessary.		
166.	**7.1.6 Organizational knowledge**		
167.	The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.		
168.	This knowledge shall be maintained and be made available to the extent necessary.		
169.	When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.		
170.	NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.		
171.	NOTE 2 Organizational knowledge can be based on:		
172.	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);		

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173.	b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).		
174.	**7.2 Competence**		
175.	The organization shall:		
176.	a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;		
177.	b) ensure that these persons are competent on the basis of appropriate education, training, or experience;		
178.	c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;		
179.	d) retain appropriate documented information as evidence of competence.		
180.	NOTE: Consideration should be given for the periodic review of the necessary competence.		
181.	NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.		
182.	**7.3 Awareness**		
183.	The organization shall ensure that persons doing work under the organization's control are aware of:		
184.	a) the quality policy;		
185.	b) relevant quality objectives;		
186.	c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;		
187.	d) the implications of not conforming with the quality management system requirements.		

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188.	e) ***relevant quality management system documented information and changes thereto;***		
189.	f) ***their contribution to product or service conformity;***		
190.	g) ***their contribution to product safety;***		
191.	h) ***the importance of ethical behavior.***		
192.	**7.4 Communication**		
193.	The organization shall determine the internal and external communications relevant to the quality management system, including:		
194.	a) on what it will communicate;		
195.	b) when to communicate;		
196.	c) with whom to communicate;		
197.	d) how to communicate;		
198.	e) who communicates.		
199.	***NOTE: Communication should include internal and external feedback relevant to the quality management system.***		
200.	**7.5 Documented information**		
201.	**7.5.1 General**		
202.	The organization's quality management system shall include: a) documented information required by this International Standard;		
203.	b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.		
204.	NOTE The extent of documented information for a quality management system can differ from one organization to another due to:		
205.	— the size of organization and its type of activities, processes, products and services;		

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206.	— the complexity of processes and their interactions;		
207.	— the competence of persons.		
208.	**7.5.2 Creating and updating**		
209.	When creating and updating documented information, the organization shall ensure appropriate:		
210.	a) identification and description (e.g. a title, date, author, or reference number);		
211.	b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);		
212.	c) review and approval for suitability and adequacy.		
213.	***NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.***		
214.	**7.5.3 Control of documented information**		
215.	**7.5.3.1** Documented information required by the quality management system and by this International Standard shall be controlled to ensure:		
216.	a) it is available and suitable for use, where and when it is needed;		
217.	b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).		
218.	**7.5.3.2** For the control of documented information, the organization shall address the following activities, as applicable:		
219.	a) distribution, access, retrieval and use;		
220.	b) storage and preservation, including preservation of legibility;		
221.	c) control of changes (e.g. version control);		
222.	d) retention and disposition.		

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223.	*e)* ***prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.***		
224.	Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.		
225.	Documented information retained as evidence of conformity shall be protected from unintended alterations.		
226.	***When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).***		
227.	NOTE 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.		
228.	**8 Operation**		
229.	**8.1 Operational planning and control**		
230.	The organization shall plan, implement and control 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:		
231.	a) determining the requirements for the products and services;		
232.	***NOTE: Determination of requirements for the products and services should include consideration of:*** – ***personal and product safety;*** – ***producibility and inspectability;*** – ***reliability, availability, and maintainability;*** – ***suitability of parts and materials used in the product;*** – ***selection and development of embedded software;*** – ***product obsolescence;***		

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	– ***prevention, detection, and removal of foreign objects;*** – ***handling, packaging, and preservation;*** – ***recycling or final disposal of the product at the end of its life.***		
233.	b) establishing criteria for: 1) the processes;		
234.	2) the acceptance of products and services;		
235.	***NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques can be used to support:*** – ***design verification (e.g., reliability, maintainability, product safety);*** – ***process control;*** • ***selection and verification of key characteristics;*** • ***process capability measurements;*** • ***statistical process control;*** • ***design of experiments;*** – ***verification;*** – ***failure mode, effects, and criticality analysis.***		
236.	c) determining the resources needed to achieve conformity to the product and service requirements ***and to meet on-time delivery of products and services***;		
237.	d) implementing control of the processes in accordance with the criteria;		
238.	e) determining, maintaining and retaining documented information to the extent necessary:		
239.	1) to have confidence that the processes have been carried out as planned;		
240.	2) to demonstrate the conformity of products and services to their requirements.		
241.	*f)* ***determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;***		

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242.	*g)* ***engaging representatives of affected organization functions for operational planning and control;***		
243.	*h)* ***determining the process and resources to support the use and maintenance of the products and services;***		
244.	*i)* ***determining the products and services to be obtained from external providers;***		
245.	*j)* ***establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.***		
246.	***NOTE: One method to achieve operational planning and control can be through using integrated phased processes.***		
247.	***As appropriate to the organization, customer requirements, and products and services, the organization shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.***		
248.	***NOTE: This activity is generally referred to as project planning, project management, or program management.***		
249.	The output of this planning shall be suitable for the organization's operations.		
250.	***NOTE: As an output of this planning, documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.***		
251.	The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.		
252.	The organization shall ensure that outsourced processes are controlled (see 8.4).		
253.	***The organization shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements.***		

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254.	***The process shall ensure that work transfer impacts and risks are managed.***		
255.	***NOTE: For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, see 8.4. For the control of work transfer from one organization facility to another, or from an external provider to the organization, see 8.5.***		
256.	***8.1.1 Operational Risk Management***		
257.	***The organization shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to the organization and the products and services:***		
258.	*a)* ***assignment of responsibilities for operational risk management;***		
259.	*b)* ***definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance);***		
260.	*c)* ***identification, assessment, and communication of risks throughout operations;***		
261.	*d)* ***identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;***		
262.	*e)* ***acceptance of risks remaining after implementation of mitigating actions.***		
263.	***NOTE 1: While clause 6.1 addresses the risks and opportunities when planning for the quality management system of the organization, the scope of this clause (8.1.1) is limited to the risks associated to the operational processes needed for the provision of products and services (clause 8).***		
264.	***NOTE 2: Within the aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.***		

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265.	***8.1.2 Configuration Management***		
266.	***The organization shall plan, implement, and control a process for configuration management as appropriate to the organization and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:***		
267.	*a)* ***control product identity and traceability to requirements, including the implementation of identified changes;***		
268.	*b)* ***ensure that the documented information (e.g., requirements, design, verification, validation and acceptance documentation) is consistent with the actual attributes of the products and services.***		
269.	***8.1.3 Product Safety***		
270.	***The organization shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to the organization and the product.***		
271.	***NOTE: Examples of these processes include:*** – ***assessment of hazards and management of associated risks (see 8.1.1);*** – ***management of safety critical items;*** – ***analysis and reporting of occurred events affecting safety;*** – ***communication of these events and training of persons.***		
272.	***8.1.4 Prevention of Counterfeit Parts***		
273.	***The organization shall plan, implement, and control processes, appropriate to the organization and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.***		
274.	***NOTE: Counterfeit part prevention processes should consider:*** – ***training of appropriate persons in the awareness and prevention of counterfeit parts;*** – ***application of a parts obsolescence monitoring program;*** – ***controls for acquiring externally provided product from original or authorized***		

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	manufacturers, authorized distributors, or other approved sources; – ***requirements for assuring traceability of parts and components to their original or authorized manufacturers;*** – ***verification and test methodologies to detect counterfeit parts;*** – ***monitoring of counterfeit parts reporting from external sources;*** – ***quarantine and reporting of suspect or detected counterfeit parts.***		
275.	**8.2 Requirements for products and services**		
276.	**8.2.1 Customer communication**		
277.	Communication with customers shall include: a) providing information relating to products and services;		
278.	b) handling enquiries, contracts or orders, including changes;		
279.	c) obtaining customer feedback relating to products and services, including customer complaints;		
280.	d) handling or controlling customer property;		
281.	e) establishing specific requirements for contingency actions, when relevant.		
282.	**8.2.2 Determining the requirements for products and services**		
283.	When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including:		
284.	1) any applicable statutory and regulatory requirements;		
285.	2) those considered necessary by the organization;		
286.	b) the organization can meet the claims for the products and services it offers.		
287.	*c)* ***special requirements of the products and services are determined;***		
288.	*d)* ***operational risks (e.g., new technology, ability and capacity to provide, short delivery time frame) have been identified.***		

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289.	**8.2.3 Review of the requirements for products and services**		
290.	**8.2.3.1** The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers.		
291.	The organization shall conduct a review before committing to supply products and services to a customer, to include:		
292.	a) requirements specified by the customer, including the requirements for delivery and post- delivery activities;		
293.	b) requirements not stated by the customer, but necessary for the specified or intended use, when known;		
294.	c) requirements specified by the organization;		
295.	d) statutory and regulatory requirements applicable to the products and services;		
296.	e) contract or order requirements differing from those previously expressed.		
297.	***This review shall be coordinated with applicable functions of the organization.***		
298.	***If upon review the organization determines that some customer requirements cannot be met or can only partially be met, the organization shall negotiate a mutually acceptable requirement with the customer.***		
299.	The organization shall ensure that contract or order requirements differing from those previously defined are resolved.		
300.	The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.		
301.	NOTE 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 catalogues.		

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302.	**8.2.3.2** The organization shall retain documented information, as applicable:		
303.	a) on the results of the review;		
304.	b) on any new requirements for the products and services.		
305.	**8.2.4 Changes to requirements for products and services**		
306.	The organization 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.		
307.	**8.3 Design and development of products and services**		
308.	**8.3.1 General**		
309.	The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.		
310.	**8.3.2 Design and development planning**		
311.	In determining the stages and controls for design and development, the organization shall consider:		
312.	a) the nature, duration and complexity of the design and development activities;		
313.	b) the required process stages, including applicable design and development reviews;		
314.	c) the required design and development verification and validation activities;		
315.	d) the responsibilities and authorities involved in the design and development process;		
316.	e) the internal and external resource needs for the design and development of products and services;		
317.	f) the need to control interfaces between persons involved in the design and development process;		

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318.	g) the need for involvement of customers and users in the design and development process;		
319.	h) the requirements for subsequent provision of products and services;		
320.	i) the level of control expected for the design and development process by customers and other relevant interested parties;		
321.	j) the documented information needed to demonstrate that design and development requirements have been met.		
322.	***When appropriate, the organization shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.***		
323.	***Design and development planning shall consider the ability to provide, verify, test and maintain products and services (reference output of 8.1a).***		
324.	**8.3.3 Design and development inputs**		
325.	The organization shall determine the requirements essential for the specific types of products and services to be designed and developed.		
326.	The organization shall consider: a) functional and performance requirements;		
327.	b) information derived from previous similar design and development activities;		
328.	c) statutory and regulatory requirements;		
329.	d) standards or codes of practice that the organization has committed to implement;		
330.	e) potential consequences of failure due to the nature of the products and services.		
331.	*f)* ***when applicable, the potential consequences of obsolescence (e.g., materials, processes, components, equipment, products).***		
332.	Inputs shall be adequate for design and development purposes, complete and unambiguous.		
333.	Conflicting design and development inputs shall be resolved.		

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334.	The organization shall retain documented information on design and development inputs.		
335.	***NOTE: The organization can also consider as design and development inputs other information such as benchmarking, external provider feedback, internally generated data, and in-service data.***		
336.	**8.3.4 Design and development controls**		
337.	The organization shall apply controls to the design and development process to ensure that:		
338.	a) the results to be achieved are defined;		
339.	b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;		
340.	c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;		
341.	d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;		
342.	e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;		
343.	f) documented information of these activities is retained.		
344.	*g)* ***progression to the next stage is authorized.***		
345.	***Participants in design and development reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.***		
346.	NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.		

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347.	***8.3.4.1 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:***		
348.	*a)* ***test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;***		
349.	*b)* ***test procedures describe the test methods to be used, how to perform the test, and how to record the results;***		
350.	*c)* ***the correct configuration of the test item is submitted for the test;***		
351.	*d)* ***the requirements of the test plan and the test procedures are observed;***		
352.	*e)* ***the acceptance criteria are met.***		
353.	***Monitoring and measuring devices used for testing shall be controlled as defined in clause 7.1.5.***		
354.	***At the completion of design and development, the organization shall ensure that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.***		
355.	**8.3.5 Design and development outputs**		
356.	The organization shall ensure that design and development outputs:		
357.	a) meet the input requirements;		
358.	b) are adequate for the subsequent processes for the provision of products and services;		
359.	c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;		
360.	d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.		

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361.	*e)* ***specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items;***		
362.	*f)* ***are approved by authorized person(s) prior to release.***		
363.	***The organization shall define the data required to allow the product to be identified, manufactured, verified, used, and maintained.***		
364.	***NOTE: Data can include:*** – ***the drawings, part lists, and specifications necessary to define the configuration and the design features of the product;*** – ***the material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service;*** – ***the technical data and repair schemes for operating and maintaining the product.***		
365.	The organization shall retain documented information on design and development outputs.		
366.	**8.3.6 Design and development changes**		
367.	The organization shall identify, review and control 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.		
368.	***The organization shall implement a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.***		
369.	The organization shall retain documented information on:		
370.	a) design and development changes;		
371.	b) the results of reviews;		
372.	c) the authorization of the changes;		
373.	d) the actions taken to prevent adverse impacts.		

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374.	***Design and development changes shall be controlled in accordance with the configuration management process requirements.***		
375.	**8.4 Control of externally provided processes, products and services**		
376.	**8.4.1 General**		
377.	The organization shall ensure that externally provided processes, products and services conform to requirements.		
378.	***The organization shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.***		
379.	***The organization shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.***		
380.	***The organization shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.***		
381.	***The organization shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.***		
382.	The organization shall determine the controls to be applied to externally provided processes, products and services when:		
383.	a) products and services from external providers are intended for incorporation into the organization's own products and services;		
384.	b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;		
385.	c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.		

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386.	The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.		
387.	The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.		
388.	***NOTE: During external provider evaluation and selection, the organization can use quality data from objective and reliable external sources, as evaluated by the organization (e.g., information from accredited quality management system or process certification bodies, external provider approvals from government authorities or customers). Use of such data would be only one element of an organization's external provider control process and the organization remains responsible for verifying that externally provided processes, products, and services meet specified requirements.***		
389.	***8.4.1.1 The organization shall:*** ***a) define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;***		
390.	***b) maintain a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family);***		
391.	***c) periodically review external provider performance including process, product and service conformity, and on-time delivery performance;***		
392.	***d) define the necessary actions to take when dealing with external providers that do not meet requirements;***		
393.	***e) define the requirements for controlling documented information created by and/or retained by external providers.***		

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394.	**8.4.2 Type and extent of control**		
395.	The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.		
396.	The organization shall:		
397.	a) ensure that externally provided processes remain within the control of its quality management system;		
398.	b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;		
399.	c) take into consideration:		
400.	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;		
401.	2) the effectiveness of the controls applied by the external provider;		
402.	*3)* ***the results of the periodic review of external provider performance (see 8.4.1.1 c);***		
403.	d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.		
404.	***Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by the organization.***		
405.	***These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.***		
406.	***NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve the organization of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.***		
407.	***NOTE 2: Verification activities can include:***		

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	– ***review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);*** – ***inspection and audit at the external provider's premises;*** – ***review of the required documentation;*** – ***review of production part approval process data;*** – ***inspection of products or verification of services upon receipt;*** – ***review of delegations of product verification to the external provider.***		
408.	***When externally provided product is released for production use pending completion of all required verification activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.***		
409.	***When the organization delegates verification activities to the external provider, the scope and requirements for delegation shall be defined***		
410.	***and a register of delegations shall be maintained.***		
411.	***The organization shall periodically monitor the external provider's delegated verification activities.***		
412.	***When external provider test reports are utilized to verify externally provided products, the organization shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements.***		
413.	***When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), the organization shall implement a process to validate the accuracy of test reports.***		
414.	**8.4.3 Information for external providers**		
415.	The organization shall ensure the adequacy of requirements prior to their communication to the external provider.		

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416.	The organization shall communicate to external providers its requirements for:		
417.	a) the processes, products and services to be provided ***including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);***		
418.	b) the approval of:		
419.	1) products and services;		
420.	2) methods, processes and equipment;		
421.	3) the release of products and services;		
422.	c) competence, including any required qualification of persons;		
423.	d) the external providers' interactions with the organization;		
424.	e) control and monitoring of the external providers' performance to be applied by the organization;		
425.	f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.		
426.	*g)* ***design and development control;***		
427.	*h)* ***special requirements, critical items, or key characteristics;***		
428.	*i)* ***test, inspection, and verification (including production process verification);***		
429.	*j)* ***the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;***		
430.	*k)* ***the need to:***		
431.	– ***implement a quality management system;***		
432.	– ***use customer-designated or approved external providers, including process sources (e.g., special processes);***		

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433.	– ***notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;***		
434.	– ***prevent the use of counterfeit parts (see 8.1.4);***		
435.	– ***notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization's approval;***		
436.	– ***flow down to external providers applicable requirements including customer requirements;***		
437.	– ***provide test specimens for design approval, inspection/verification, investigation, or auditing;***		
438.	– ***retain documented information, including retention periods and disposition requirements;***		
439.	*l)* ***the right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;***		
440.	*m)* ***ensuring that persons are aware of:***		
441.	– ***their contribution to product or service conformity;***		
442.	– ***their contribution to product safety;***		
443.	– ***the importance of ethical behavior.***		
444.	**8.5 Production and service provision**		
445.	**8.5.1 Control of production and service provision**		
446.	The organization shall implement production and service provision under controlled conditions.		

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447.	Controlled conditions shall include, as applicable: a) the availability of documented information that defines:		
448.	1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;		
449.	2) the results to be achieved;		
450.	***NOTE 1: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts list, materials, and process specifications.***		
451.	***NOTE 2: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents (e.g., manufacturing plans, travelers, routers, work orders, process cards), and verification documents.***		
452.	b) the availability and use of suitable monitoring and measuring resources;		
453.	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;		
454.	***1. ensuring that documented information for monitoring and measurement activity for product acceptance includes:***		
455.	– ***criteria for acceptance and rejection;***		
456.	– ***where in the sequence verification operations are to be performed;***		
457.	– ***measurement results to be retained (at a minimum an indication of acceptance or rejection);***		
458.	– ***any specific monitoring and measurement equipment required and instructions associated with their use;***		

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459.	***2. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).***		
460.	d) the use of suitable infrastructure and environment for the operation of processes;		
461.	***NOTE: Suitable infrastructure can include product specific tools (e.g., jigs, fixtures, molds) and software programs.***		
462.	e) the appointment of competent persons, including any required qualification;		
463.	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;		
464.	***NOTE: These processes can be referred to as special processes (see 8.5.1.2).***		
465.	g) the implementation of actions to prevent human error;		
466.	h) the implementation of release, delivery and post-delivery activities.		
467.	*i)* ***the establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);***		
468.	*j)* ***the accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);***		
469.	*k)* ***the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;***		
470.	*l)* ***the determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);***		
471.	*m)* ***the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;***		

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472.	*n)* ***the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;***		
473.	*o)* ***the provision for the prevention, detection, and removal of foreign objects;***		
474.	*p)* ***the control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements (see 7.1.3);***		
475.	*q)* ***the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.***		
476.	***8.5.1.1 Control of Equipment, Tools, and Software Programs***		
477.	***Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production***		
478.	***and shall be maintained.***		
479.	***Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.***		
480.	***8.5.1.2 Validation and Control of Special Processes***		
481.	***For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organization shall establish arrangements for these processes including, as applicable:***		
482.	***a) definition of criteria for the review and approval of the processes;***		
483.	***b) determination of conditions to maintain the approval;***		
484.	***c) approval of facilities and equipment;***		
485.	***d) qualification of persons;***		

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486.	***e) use of specific methods and procedures for implementation and monitoring of the processes;***		
487.	***f) requirements for documented information to be retained.***		
488.	***8.5.1.3 Production Process Verification***		
489.	***The organization shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.***		
490.	***NOTE: These activities can include risk assessments, capacity studies, capability studies, and control plans.***		
491.	***The organization shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation, and tooling are able to produce parts and assemblies that meet requirements.***		
492.	***This activity shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, production process changes, tooling changes).***		
493.	***NOTE: This activity can be referred to as First Article Inspection (FAI).***		
494.	***The organization shall retain documented information on the results of production process verification.***		
495.	**8.5.2 Identification and traceability**		
496.	The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.		
497.	***The organization shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.***		
498.	The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.		

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499.	***When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish controls for the media.***		
500.	The organization shall control the unique identification of the outputs when traceability is a requirement,		
501.	and shall retain the documented information necessary to enable traceability.		
502.	***NOTE: Traceability requirements can include:*** – ***the identification to be maintained throughout the product life;*** – ***the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);*** – ***for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;*** – ***for a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.***		
503.	**8.5.3 Property belonging to customers or external providers**		
504.	The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.		
505.	The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.		
506.	When the 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		
507.	and retain documented information on what has occurred.		
508.	NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.		
509.	**8.5.4 Preservation**		

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510.	The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.		
511.	NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.		
512.	***Preservation of outputs shall also include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:***		
513.	***a) cleaning;***		
514.	***b) prevention, detection, and removal of foreign objects;***		
515.	***c) special handling and storage for sensitive products;***		
516.	***d) marking and labeling, including safety warnings and cautions;***		
517.	***e) shelf life control and stock rotation;***		
518.	***f) special handling and storage for hazardous materials.***		
519.	**8.5.5 Post-delivery activities**		
520.	The organization shall meet requirements for post-delivery activities associated with the products and services.		
521.	In determining the extent of post-delivery activities that are required, the organization shall consider:		
522.	a) statutory and regulatory requirements;		
523.	b) the potential undesired consequences associated with its products and services;		
524.	c) the nature, use and intended lifetime of its products and services;		
525.	d) customer requirements;		
526.	e) customer feedback.		
527.	*f)* ***collection and analysis of in-service data (e.g., performance, reliability, lessons learned);***		

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528.	*g)* ***control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;***		
529.	*h)* ***controls required for work undertaken external to the organization (e.g., off- site work);***		
530.	*i)* ***product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).***		
531.	***When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.***		
532.	NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.		
533.	**8.5.6 Control of changes**		
534.	The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.		
535.	***Persons authorized to approve production or service provision changes shall be identified.***		
536.	***NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.***		
537.	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.		
538.	**8.6 Release of products and services**		
539.	The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.		
540.	The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.		

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541.	The organization shall retain documented information on the release of products and services.		
542.	The documented information shall include: a) evidence of conformity with the acceptance criteria;		
543.	b) traceability to the person(s) authorizing the release.		
544.	***When required to demonstrate product qualification, the organization shall ensure that retained documented information provides evidence that the products and services meet the defined requirements.***		
545.	***The organization shall ensure that all documented information required to accompany the products and services are present at delivery.***		
546.	**8.7 Control of nonconforming outputs**		
547.	**8.7.1** The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.		
548.	***NOTE: The term "nonconforming outputs" includes nonconforming product or service generated internally, received from an external provider, or identified by a customer.***		
549.	The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.		
550.	This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.		
551.	***The organization's nonconformity control process shall be maintained as documented information including the provisions for:***		
552.	– ***defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;***		
553.	– ***taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;***		

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554.	– ***timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;***		
555.	– ***defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts (see 10.2).***		
556.	***NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.***		
557.	The organization shall deal with nonconforming outputs in one or more of the following ways:		
558.	a) correction;		
559.	b) segregation, containment, return or suspension of provision of products and services;		
560.	c) informing the customer;		
561.	d) obtaining authorization for acceptance under concession ***by a relevant authority and, when applicable, by the customer.***		
562.	***Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:***		
563.	– ***after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;***		
564.	– ***after authorization by the customer, if the nonconformity results in a departure from the contract requirements.***		
565.	***Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.***		
566.	***Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.***		

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567.	Conformity to the requirements shall be verified when nonconforming outputs are corrected.		
568.	**8.7.2** The organization shall retain documented information that:		
569.	a) describes the nonconformity;		
570.	b) describes the actions taken;		
571.	c) describes any concessions obtained;		
572.	d) identifies the authority deciding the action in respect of the nonconformity.		
573.	**9 Performance evaluation**		
574.	**9.1 Monitoring, measurement, analysis and evaluation**		
575.	**9.1.1 General**		
576.	The organization shall determine:		
577.	a) what needs to be monitored and measured;		
578.	b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;		
579.	c) when the monitoring and measuring shall be performed;		
580.	d) when the results from monitoring and measurement shall be analysed and evaluated.		
581.	The organization shall evaluate the performance and the effectiveness of the quality management system.		
582.	The organization shall retain appropriate documented information as evidence of the results.		
583.	**9.1.2 Customer satisfaction**		
584.	The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.		

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585.	The organization shall determine the methods for obtaining, monitoring and reviewing this information.		
586.	NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.		
587.	***Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests.***		
588.	***The organization shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.***		
589.	**9.1.3 Analysis and evaluation**		
590.	The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.		
591.	***NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).***		
592.	The results of analysis shall be used to evaluate:		
593.	a) conformity of products and services;		
594.	b) the degree of customer satisfaction;		
595.	c) the performance and effectiveness of the quality management system;		
596.	d) if planning has been implemented effectively;		
597.	e) the effectiveness of actions taken to address risks and opportunities		
598.	f) the performance of external providers;		
599.	g) the need for improvements to the quality management system.		

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600.	NOTE Methods to analyse data can include statistical techniques.		
601.	**9.2 Internal audit**		
602.	**9.2.1** The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:		
603.	a) conforms to:		
604.	1) the organization's own requirements for its quality management system;		
605.	***NOTE: The organization's own requirements should include customer and applicable statutory and regulatory quality management system requirements***		
606.	2) the requirements of this International Standard;		
607.	b) is effectively implemented and maintained.		
608.	***NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.***		
609.	**9.2.2** The organization shall:		
610.	a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;		
611.	b) define the audit criteria and scope for each audit;		
612.	c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;		
613.	d) ensure that the results of the audits are reported to relevant management;		
614.	e) take appropriate correction and corrective actions without undue delay;		
615.	f) retain documented information as evidence of the implementation of the audit program and the audit results.		

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616.	NOTE See ISO 19011 for guidance.		
617.	**9.3 Management Review**		
618.	**9.3.1 General**		
619.	Top management 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.		
620.	**9.3.2 Management review inputs**		
621.	The management review shall be planned and carried out taking into consideration:		
622.	a) the status of actions from previous management reviews;		
623.	b) changes in external and internal issues that are relevant to the quality management system;		
624.	c) information on the performance and effectiveness of the quality management system, including trends in:		
625.	1) customer satisfaction and feedback from relevant interested parties;		
626.	2) the extent to which quality objectives have been met;		
627.	3) process performance and conformity of products and services;		
628.	4) nonconformities and corrective actions;		
629.	5) monitoring and measurement results;		
630.	6) audit results;		
631.	7) the performance of external providers;		
632.	*8)* ***on-time delivery performance;***		
633.	d) the adequacy of resources;		
634.	e) the effectiveness of actions taken to address risks and opportunities (see 6.1);		
635.	f) opportunities for improvement.		

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636.	**9.3.3 Management review outputs**		
637.	The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement;		
638.	b) any need for changes to the quality management system;		
639.	c) resource needs.		
640.	*d)* ***risks identified.***		
641.	The organization shall retain documented information as evidence of the results of management reviews.		
642.	**10 Improvement**		
643.	**10.1 General**		
644.	The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.		
645.	These shall include: a) improving products and services to meet requirements as well as to address future needs and expectations;		
646.	b) correcting, preventing or reducing undesired effects;		
647.	c) improving the performance and effectiveness of the quality management system.		
648.	NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.		
649.	**10.2 Nonconformity and corrective action**		
650.	**10.2.1** When a nonconformity occurs, including any arising from complaints, the organization shall:		
651.	a) react to the nonconformity and, as applicable:		
652.	1) take action to control and correct it;		

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653.	2) deal with the consequences;		
654.	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:		
655.	1) reviewing and analysing the nonconformity;		
656.	2) determining the causes of the nonconformity including***, as applicable, those related to human factors***;		
657.	3) determining if similar nonconformities exist, or could potentially occur;		
658.	c) implement any action needed;		
659.	d) review the effectiveness of any corrective action taken;		
660.	e) update risks and opportunities determined during planning, if necessary;		
661.	f) make changes to the quality management system, if necessary.		
662.	*g)* ***flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;***		
663.	*h)* ***take specific actions when timely and effective corrective actions are not achieved.***		
664.	Corrective actions shall be appropriate to the effects of the nonconformities encountered.		
665.	***The organization shall maintain documented information that defines the nonconformity and corrective action management processes.***		
666.	**10.2.2** The organization shall retain documented information as evidence of:		
667.	a) the nature of the nonconformities and any subsequent actions taken;		
668.	b) the results of any corrective action.		

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669.	**10.3 Continual improvement**		
670.	The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.		
671.	The organization 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.		
672.	***The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.***		
673.	***NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.***		