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~~**Текст**~~ – исключённый текст
Текст – изменённый текст
Текст ISO/FDIS 9001:2026 на русском в переводе А. Горбунова

Структура

Красным отмечены разделы и пункты, в которых есть изменения, вне зависимости от объёма этих изменений: изменено ли одно слово, порядок слов или введён/удалён фрагмент текста.

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Во всём тексте заменено «this International Standard» на «this document»

Знак «…» означает совпадающий в обеих редакциях текст. Для экономии места и удобства чтения сам текст не повторяется.

Принимая во внимание, что текст приложения А был изменён кардинальным образом, сравнение содержания с вариантом 2015 года не делалось, только показано изменение структуры (см. в конце).
Приложение В исключено

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Foreword … ~~**The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.**~~ This ~~**fifth**~~ edition cancels and replaces the ~~**fourth**~~ edition (ISO 9001:2008), which has been technically revised~~**, through the adoption of a revised clause sequence and the adaptation of the revised quality management principles and of new concepts. It also cancels and replaces the Technical Corrigendum ISO 9001:2008/Cor.1:2009.**~~	**Foreword** … **This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*, in collaboration with European Committee for Standardization (CEN) in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement)**. This **six** edition cancels and replaces the **fifth** edition (ISO 9001:2015), which has been technically revised. **It also incorporates the Amendment ISO 9001:2015/Amd 1:2024.** **The main changes are as follows:** **— Inclusion of core ISO management system terms and definitions: Clause 3 of the document now includes a limited number of terms and definitions. ISO 9000 remains the normative reference for all quality management terms and definitions.** **— Introduction of quality culture and ethical behaviour: Quality culture and ethical behaviour are now addressed within the requirements, particularly in relation to leadership, awareness and the environment for the operation of processes.** **— Separation of risks and opportunities: Risks and opportunities are more clearly distinguished, with separate consideration of actions to address each.** **— Strengthened management of change: Requirements related to changes to the quality management system have been reinforced to support the achievement of intended results.** **— Enhanced explanatory content in Annex A: It has been revised to provide enhanced clarification of the structure, terminology and intent of the requirements as informative text, without introducing additional requirements.** **— Removal of Annex B: It previously provided information on other ISO/TC 176 standards. References to these standards are now included in Annex A and on the ISO/TC 176 website.** **Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.**
Introduction **0.1 General** ~~**The adoption**~~ of a quality management system is a strategic decision for an	**Introduction** **0.1 General** **Establishing and implementing** of a quality management system is a strategic

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organization that ~~can help to improve its overall performance and provide a sound basis for sustainable development initiatives.~~ The potential benefits to an organization of implementing a quality management system based on ~~this International Standard~~ are: a) – d) … … ~~It is not the intent of this International Standard to imply~~ the need for: … ~~This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.~~ ~~The process approach enables an organization to plan its processes and their interactions.~~ ~~The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.~~ ~~Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).~~ Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization ~~might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization~~. ~~In this International Standard, the following verbal forms are used:~~ ~~— "shall" indicates a requirement;~~ ~~— "should" indicates a recommendation;~~ ~~— "may" indicates a permission;~~ ~~— "can" indicates a possibility or a capability.~~ ~~Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.~~	decision for an organization that **supports improved performance, enhances customer satisfaction, and provides a foundation for sustained success and** sustainable development initiatives. The potential benefits to an organization of implementing a quality management system based on **the requirements in this document** are: a) – d) … … **This document does not imply** the need for: … Consistently meeting requirements and addressing future needs and expectations **of customers and other relevant interested parties** poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization **can pursue continual improvement in various ways, such as incremental or breakthrough change, innovation and reorganization initiatives**. **Annex A provides information and clarifications that can support understanding of the structure, terms and clauses of this document. It does not contain any additional requirements.** **For guidance on the application of all clauses in this document, see ISO/DIS 9002** [1],
0.2 Quality managements principles This ~~International Standard~~ is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of	**0.2 Quality managements principles** This **document** is based on the quality management principles described in ISO 9000[2]. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated

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benefits associated with the principle and examples of ~~typical~~ actions to improve the organization’s performance when applying the principle. …	with the principle and examples of actions to improve the organization’s performance when applying the principle. …
0.3 Process approach **0.3.1 General** This ~~International Standard~~ promotes the adoption of a process approach when ~~developing~~, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. … The process approach involves the systematic ~~definition~~ and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see ~~0.3.3~~) aimed ~~at taking advantage of opportunities and preventing undesirable results.~~ … a) … b) ~~the~~ consideration of processes in terms of added value c) ~~the~~ achievement of effective process performance d) improvement of processes based on evaluation of data and information. Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks. **Figure 1— Schematic representation of the elements of a single process**	**0.3 Process approach** **0.3.1 General** This **document** promotes the adoption of a process approach when **establishing**, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. **Specific requirements considered essential to the application of a process approach are included in 4.4.** … The process approach involves the systematic **determination** and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization Management of the processes and the system as a whole can be achieved using the **Plan-Do-Check-Act** (PDCA) cycle (see 0.3.2) with an overall focus on risk-based thinking (see **A.6.1.2**) aimed **at pursuing desired results by taking advantage of opportunities**. … a) … b) consideration of processes in terms of **risk, opportunity and** added value c) achievement of effective process performance d) improvement of processes based on **the results of** evaluation of data and information. Figure 1 gives a schematic representation of any **single** process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the **process steps and** related risks. **Figure 1 — Schematic representation of the elements of a single process** **(рисунок изменён)**
0.3.2 Plan-Do-Check-Act cycle The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle. **Figure 2 — Representation of the structure of this International Standard in the PDCA cycle** The PDCA cycle can be briefly described as follows: — Plan: establish the objectives of the system and its processes, and the resources	**0.3.2 Plan-Do-Check-Act cycle** The PDCA cycle can be briefly described as follows: — Plan: Establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customer **and other relevant interested party** requirements and the organization’s policies, and **determine** and address risks and opportunities; — Do: Implement what was planned; — Check: Monitor and (where applicable) measure processes and the resulting

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needed to deliver results in accordance with customer~~s'~~ requirements and the organization's policies, and ~~identify~~ and address risks and opportunities; — Do: implement what was planned; — Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results; — Act: take actions to improve performance~~, as necessary~~.	products and services against policies, objectives, requirements and planned activities, and report the results; — Act: Take actions to improve performance **of the quality management system**. The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle. **Figure 2 — Representation of the structure of this International Standard in the PDCA cycle (рисунок изменён)**
0.3.3 Risk-based thinking	— **(раздел удалён)**
0.4 Relationship with other management system standards ~~**This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).**~~	0.4 Relationship with other management system standards **This document applies the harmonized approach as published in the ISO/IEC Directives related to the development of management system standards (MSS). The intention is to support alignment and facilitate the integration of the requirements and recommendations of one or more MSS into an organization's management system.** **For more information, see https://www.iso.org/management-system-standards.html.**
~~**This International Standard enables an organization to use**~~ the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards. ~~**This International Standard relates to ISO 9000 and ISO 9004 as follows:**~~ ~~**— ISO 9000 Quality management systems — Fundamentals and vocabulary provides essential background for the proper understanding and implementation of this International Standard;**~~ ~~**— ISO 9004 Managing for the sustained success of an organization — A quality management approach provides guidance for organizations that choose to progress beyond the requirements of this International Standard.**~~ ~~**Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.**~~	This document provides a basis for an organization to apply the process approach, coupled with the PDCA cycle, risk-based thinking **and opportunity-based thinking, in order** to align or integrate its quality management system with the requirements of other management system standards. **This document relates to the following standards:** **— [2] - provides the fundamental concepts and vocabulary essential for understanding the requirements of this document;** **— [1] - provides guidelines on the application of the requirements of this document.** **— [3] - provides guidance on enhancing the quality of an organization and its ability to achieve sustained success.**
This ~~**International Standard**~~ does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or ~~**financial**~~ management. Sector-specific quality management system standards based on the requirements of this ~~**International Standard**~~ have been developed ~~**for a number of sectors**~~. Some	This **document** does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or **asset** management. Sector-specific ISO quality management system standards based on the requirements of this **document** have been developed. Some of these standards

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of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this ~~**International Standard**~~ within the particular sector. ~~**A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.**~~	specify additional quality management system requirements, while others are limited to providing guidance to the application of this **document** within the particular sector. **NOTE See https: //www.iso.org/management-system-standards-list.html[4] for a list of all management system standards.**
1 Scope All the requirements of this ~~**International Standard**~~ are generic ~~**and are intended to be**~~ applicable to any organization, regardless of its type or size, or the products and services it provides.	**1 Scope** All the requirements of this **document** are generic. **This document is** applicable to any organization, regardless of its type or size, or the products and services it provides.
2 Normative references The following documents~~**, in whole or in part, are normatively referenced in this document and are indispensable for its application**~~.	**2 Normative references** The following documents **are referred to in the text in such a way that some or all of their content constitutes requirements of this document**.
3 Terms and definitions For the purposes of this document, the terms and definitions given in ISO 9000**:2015** apply. —	**3 Terms and definitions** For the purposes of this document, the terms and definitions given in ISO 9000 **and the following** apply. **ISO and IEC maintain terminology databases for use in standardization at the following addresses:** **ISO Online browsing platform: available at https://www.iso.org/obp** **-IEC Electropedia: available at https://www. electropedia.org** **3.1 – 3.20**
4 Context of the organization **4.1 Understanding the organization and its context** … — … NOTE 2 Understanding the external context can be facilitated by considering legal, technological, competitive, market, cultural, ~~**political**~~, social, economic and ~~**environmental**~~ issues at the international, national, regional or local ~~**level**~~. NOTE 3 Understanding the internal context can be facilitated by considering issues related to ~~**the organization's**~~ values, culture, knowledge and performance.	**4 Context of the organization** **4.1 Understanding the organization and its context** … **The organization shall determine whether information about climate change is a relevant issues.** … 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. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance **of the organization**.
4.2 Understanding the needs and expectations of interested parties ~~**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: a) …	**4.2 Understanding the needs and expectations of interested parties** The organization shall determine: a) …

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b) the requirements of these interested parties ~~that are relevant to the quality management system~~ …	b) the relevant requirements of these interested parties **c) which of these requirements will be addressed through the quality management system.** **…** **NOTE Relevant interested parties can have requirements related to climate change**
4.3 Determining the scope of the quality management system … a) … b) the requirements ~~of relevant interested parties~~ referred to in 4.2 c) … … The scope ~~of the organization's quality management system~~ shall be available ~~and be maintained~~ as documented information. The scope shall state the types of products and services covered, ~~and provide~~ justification for any requirement of this ~~International Standard~~ that the organization determines is not applicable to ~~the scope of~~ its quality management system. 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.	**4.3 Determining the scope of the quality management system** … a) … b) the requirements referred to in 4.2; c) … … The scope shall state the types of products and services covered. **The scope shall include** justification for any requirement of this **document** that the organization determines is not applicable to its quality management system. The scope shall be available as documented information. Conformity to this **document can** 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.
4.4 Quality management system and its processes **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 Standard~~. The organization shall determine the processes needed for the quality management system and their application throughout the organization~~, and shall~~: a) – h) … **4.4.2** To the extent necessary, ~~the organization shall~~: ~~a) maintain documented information~~ to support the operation of ~~its~~ processes; ~~b) retain documented information to have confidence~~ that the processes are being carried out as planned.	**4.4 Quality management system and its processes** **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 **document**. The organization shall: a) determine the processes needed for the quality management system and their application throughout the organization b) –i)… **4.4.2 Documented information shall be available** to the extent necessary: a) to support the operation of **the organization's** processes; b) **as evidence** that the processes are being carried out as planned.
5 Leadership **5.1 Leadership and commitment** **5.1.1 General** … a) …	**5 Leadership** **5.1 Leadership and commitment** **5.1.1 General** … l) …

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b) ensuring that the quality policy and quality objectives are established ~~for the quality management system~~ and are compatible with the ~~context and~~ strategic direction of the organization; c) … d) promoting the use of the process approach and risk-based thinking; e) – g) … h) ~~engaging,~~ directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant ~~management~~ roles to demonstrate their leadership as it applies to their areas of responsibility 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~~.	a) ensuring that the quality policy and quality objectives are established and are compatible with the strategic direction of the organization; b) … j) promoting the use of the process approach k) promoting and risk-based thinking **and opportunity-based thinking** c) – e) … f) directing and supporting persons to contribute to the effectiveness of the quality management system; g) promoting **continual** improvement; h) supporting other relevant roles to demonstrate their leadership as it applies to their areas of responsibility i) **promoting quality culture and ethical behaviour** NOTE **1** Reference to “business” in this **document** can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence **NOTE 2 An organization’s quality culture and ethical behaviour are reflected in its shared values, attitudes, practices and actions**
5.1.2 Customer focus	**5.1.2 Customer focus** (без изменений)
5.2 Policy **5.2.1 Establishing the quality policy** Top management shall establish~~, implement and maintain~~ a quality policy that: a) is appropriate to the purpose ~~and~~ context of the organization and supports its strategic direction; b) … c) includes a commitment to ~~satisfy~~ applicable requirements; d) ,,,	**5.2 Quality policy** **5.2.1** Top management shall establish a quality policy that: a) is appropriate to the purpose of the organization; b) ... c) includes a commitment to **meet** applicable requirements; d) ... **e) takes into account** the context of the organization and supports its strategic direction
5.2.2 Communicating the quality policy The quality policy shall: a) be available ~~and be maintained~~ as documented information; b) be communicated~~, understood and applied~~ within the organization; c) be available to ~~relevant~~ interested parties, as appropriate	 **5.2.2** The quality policy shall: a) be available as documented information; b) be communicated within the organization; c) be available to interested parties, as appropriate **d) be implemented, understood and applied within organization**.
5.3 Organizational roles, responsibilities and authorities Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated ~~and understood~~ within the organization. … a) ensuring that the quality management system conforms to the requirements of	**5.3 Organizational roles, responsibilities and authorities** Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization. … a) ensuring that the quality management system conforms to the requirements of

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this ~~**International Standard**~~ b) … c) reporting on the performance of the quality management system ~~**and**~~ on opportunities for improvement ~~**(see 10.1), in**~~ particular to top management; d) … e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented	this **document** c) … b) reporting on the performance of the quality management system to top management; e) **reporting on opportunities for improvement particular to top management**; d) … **f)** ensuring that the integrity of the quality management system is maintained **including** when changes to the quality management system are planned and implemented
6 Planning **6.1 Actions to address risks and opportunities** **6.1.1** When planning for the quality management system, 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: a) ... b) enhance ~~**desirable**~~ effects c) … d) achieve improvement.	**6 Planning** **6.1 Actions to address risks and opportunities** **6.1.1 Determining risks and opportunities** 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: a) … d) enhance **desired** effects b) … c) achieve **continual** improvement
6.1.2 The organization shall plan: a) actions to address these risks ~~**and opportunities**~~; b) how to: 1) integrate and implement the actions into its quality management system processes ~~**(see 4.4);**~~ 2) evaluate the effectiveness of these actions. Actions taken ~~**to address risks and opportunities**~~ shall be proportionate to the potential impact on the ~~**conformity of products and services**~~. ~~**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.**~~ ~~**NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building**~~	**6.1.2 Actions to address risks** **The organization shall determine, analyse and evaluate risks that can have an undesired effect on its ability to continually and consistently provide conforming products and services and enhance customer satisfaction.** The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes; 2) evaluate the effectiveness of these actions. Actions taken shall be proportionate to the potential impact **of the risks** on the **intended results of the quality management system**. NOTE 2 **Actions** 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 **NOTE 1 Determined risks can include risks related to the ability to provide conforming products and services during and after a disruption.**

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~~**partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.**~~	
	6.1.3 Actions to address opportunities **The organization shall determine, analyse and evaluate opportunities that can have a desired effect on its ability to continually an consistently provide conforming products and services and enhance customer satisfaction**
6.2 Quality objectives and planning to achieve them **6.2.1** The organization shall establish quality objectives at relevant functions, levels and processes ~~**needed for the quality management system.**~~ … a) – c) … d) be relevant to conformity of products and services and to ~~**enhancement**~~ of customer satisfaction; e) - g) … ~~**The organization shall maintain documented information on the quality objectives.**~~	**6.2 Quality objectives and planning to achieve them** **6.2.1** The organization shall establish quality objectives at relevant functions, levels and processes … a) – c) … h) be relevant to conformity of products and services and to **enhance** of customer satisfaction; d) - f) … g) **be available as documented information**
6.2.2	**6.2.2** (без изменений)
6.3 Planning of changes 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)**~~. The organization shall consider: a) … b) the integrity of the quality management system; c) the availability of resources; d) ...	**6.3 Planning of changes** When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner **To ensure changes are implemented effectively to achieve intended results** the organization shall consider: a) … b) **the potential impact on** the integrity of the quality management system c) the availability of resources **and information**; d) … **e) the communication of the changes** **f) how the effectiveness of the changes will be monitored and evaluated** **g) how the results of the changes will be reviewed.**
7 Support **7.1 Resources** **7.1.1 General** **7.1.2 People**	**7 Support** **7.1 Resources** **7.1.1 General** (без изменений) **7.1.2 People** (без изменений)

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7.1.3 Infrastructure … NOTE Infrastructure can include: a) – d) …	**7.1.3 Infrastructure** … NOTE **For all types of work (e.g. on site, remote or a combination thereof)** infrastructure can include: a) – d) …
7.1.4 Environment for the operation of processes … NOTE A suitable environment can be a combination of human and physical factors, such as: a) – c) … ~~**These**~~ factors can ~~**differ substantially depending on the products and services provided**~~.	**7.1.4 Environment for the operation of processes** … NOTE A suitable environment can **include** a combination of factors, **which can differ depending on the products and services provided. Relevant factors can include:** a) – c) … **Some** factors can **be influenced by the organizational quality culture and ethical behavior**.
7.1.5 Monitoring and measuring resources **7.1.5.1 General** … ~~**The organization shall retain**~~ appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.	**7.1.5 Monitoring and measuring resources** **7.1.5.1 General** … Appropriate documented information **shall be available** as evidence of fitness for purpose of the monitoring and measurement resources.
7.1.5.2 Measurement traceability When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be ~~**retained**~~ as documented information; b) identified in order to determine ~~**their**~~ status; c) safeguarded from adjustments, damage or deterioration that ~~**would invalidate the calibration status and subsequent**~~ measurement results. 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, and shall take appropriate action as necessary.	**7.1.5.2 Traceability of measurement results** When **traceability of measurement** 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: 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 **available** as documented information; b) identified in order to determine its **calibration or verification** status; c) safeguarded from adjustments, damage or deterioration that **can invalidate** measurement results. When **measurement** equipment is found to be unfit for its intended purpose, the organization shall determine **whether** the validity of previous results has been adversely affected and shall take appropriate action as necessary
7.1.6 Organizational knowledge The organization shall determine the knowledge necessary for the operation of its processes and to achieve ~~**conformity of products and services**~~. This knowledge shall be ~~**maintained and be made available**~~ to the extent necessary. …	**7.1.6 Organizational knowledge** The organization shall determine the knowledge necessary for the operation of its processes and to achieve the **intended results of its quality management system.** This knowledge shall be **retained, applied and shared** to the extent necessary. …

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~~**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.**~~ ~~**NOTE 2 Organizational knowledge can be based on:**~~ ~~**a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);**~~ ~~**b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).**~~	**NOTE Organizational knowledge can take different forms, such as:** **— experience-based knowledge held by people;** **— knowledge acquired through education, training and learning from others;** **— knowledge embedded in methods, processes and products;** **— knowledge represented in documented information, digital systems and other media.**
7.2 Competence … a) determine the necessary competence of person(s) doing work under its control that affects the performance ~~**and effectiveness**~~ of the quality management system; b) - c) … d) ~~**retain**~~ appropriate documented information as evidence of competence. NOTE …	**7.2 Competence** … a) determine the necessary competence of person(s) doing work under its control that affects its quality management system performance; b) - c) … Appropriate documented **information shall be available** as evidence of competence NOTE …
7.3 Awareness … a) … b) … c) … d) …	**7.3 Awareness** … a) … d) … b) … c) … **e) the organizational quality culture and ethic behaviour**
7.4 Communication	**7.4 Communication** (без изменений)
7.5 Documented information **7.5.1 General**	**7.5 Documented information** **7.5.1 General** (без изменений)
7.5.2 Creating and updating ,,,	**7.5.2 Creating and updating documented information** …
7.5.3 Control of documented information **7.5.3.1** … **7.5.3.2** … … Documented information ~~**retained**~~ as evidence of conformity shall be protected from unintended alterations. NOTE …	**7.5.3 Control of documented information** **7.5.3.1** … **7.5.3.2** … … Documented information **available** as evidence of conformity shall be protected from unintended alterations. NOTE …

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8 Operation **8.1 Operational planning and control** 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: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) … d) … e) ~~**determining, maintaining and retaining**~~ documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) ~~**to demonstrate**~~ the conformity of products and services ~~**to their requirements**~~. ~~**The output of this planning shall be suitable for the organization's operations.**~~ The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that ~~outsourced~~ processes are controlled (see 8.4).	**8 Operation** **8.1 Operational planning and control** The organization shall plan, implement and control the processes needed to meet requirements for the provision of products and services, and to implement the actions determined in 6, by: a) determining the requirements for the products and services **(see 8.2);** b) establishing criteria for the acceptance of products and services c) establishing criteria for the processes; c) … d) … Documented information **shall be available** to the extent necessary to have confidence that the processes have been carried out as planned. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that **externally provided** processes, **products or services that are relevant to the quality management system** are controlled (see 8.4). Documented information **shall be available** to the extent necessary **as evidence of** the conformity of products and services.
8.2 Requirements for products and services **8.2.1 Customer communication** … a) - d) … e) ~~**establishing specific requirements for**~~ contingency actions, when relevant	**8.2 Requirements for products and services** **8.2.1 Customer communication** … a) - d) … e) **providing information related to** contingency actions, when relevant, **including any related to disruptions to the provision of products or services**
8.2.2 Determining the requirements for products and services … a) … b) ~~**the organization**~~ can meet the claims for the products and services it offers	**8.2.2 Determining the requirements for products and services** … a) … b) **it** can meet the claims for the products and services it offers
8.2.3 Review of ~~the~~ requirements for products and services **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. The organization shall conduct a review before committing to supply products and services to a customer, ~~**to**~~ include: a) requirements ~~**specified**~~ by the customer, including ~~**the**~~ requirements for delivery and post-delivery activities; b) requirements not ~~**stated**~~ by the customer, but necessary for the specified or	**8.2.3 Review of requirements for products and services** **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. Before committing to supply products and services to a customer the organization shall conduct a review that includes: a) requirements **defined** by the customer, including requirements for delivery and post-delivery activities **when applicable**; b) requirements not **defined** by the customer, but necessary for the specified or

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intended use, when known; c) - e) … … ~~The customer's requirements~~ shall ~~be confirmed by~~ the organization before acceptance, when the customer does not provide a documented statement of their requirements. NOTE … **8.2.3.2** The organization shall ~~retain~~ documented information, as applicable: a) ~~on~~ the results of the review; b) ~~on~~ any new requirements for the products and services.	intended use, when known; c) - e) … … When customer does not provide a documented statement of their requirements the organization shall **confirm** the customer requirements before acceptance NOTE … **8.2.3.2** Documented information shall be **available**, as applicable, **as evidence**: a) the results of the review; b) any new **or changed** requirements for the products and services.
8.2.4 Changes to requirements for products and services 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.	**8.2.4 Changes to requirements for products and services** When requirements for products and services are changed the organization shall ensure that relevant documented information is **updated and communicated to the relevant interested parties**
8.3 Design and development of products and services **8.3.1 General** …	**8.3 Design and development of products and services** **8.3.1 General** … **NOTE The design and development process can include cycles of review, verification, validation and feedback, allowing for an iterative approach throughout the design and development stages**
8.3.2 Design and development planning In determining the stages and controls for design and development, the organization shall consider: a) – f) ~~the~~… g) the need for involvement of customers and ~~users~~ in the design and development process h) ~~the~~ requirements for subsequent provision of products and services i) ~~the~~… j) the documented information needed ~~to demonstrate~~ that design and development requirements have been met	**8.3.2 Design and development planning** In determining the stages and controls for design and development, the organization shall consider **the**: a) –f) … g) need for involvement of customers and **other relevant interested parties** in the design and development process h) requirements for **the** subsequent provision of products and services i) … j) documented information needed **as evidence** that design and development requirements have been met
8.3.3 Design and development inputs … a) – c) … d) standards or codes of practice that ~~the organization~~ has committed to implement e) … Inputs shall be adequate for design and development purposes, complete and unambiguous	**8.3.3 Design and development inputs** … a) – c) … d) standards or codes of practice that **it** has committed to implement e) **the** … Inputs shall be complete, unambiguous and adequate for design and development purposes

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8.3.4 Design and development controls … a) – d) … e) ~~**any**~~ necessary actions are taken ~~**on**~~ problems determined during the reviews, or verification and validation activities; f) documented information of these activities is ~~**retained**~~ NOTE …	**8.3.4 Design and development controls** … a) – d) … e) necessary actions are taken **to address** problems determined during the reviews, or verification and validation activities; f) documented information is **available as evidence** of these activities NOTE …
8.3.5 Design and development outputs … a) – c) … d) specify the characteristics of the products and services that are essential for their intended purpose ~~**and**~~ their safe and proper provision ~~**The organization shall retain documented information on design and development outputs**~~	**8.3.5 Design and development outputs** … a) – c) … d) specify the characteristics of the products and services **and the information on the products and services**, that are essential for their intended purpose **including** their safe and proper provision **Documented information shall be available as evidence of design and development outputs**
8.3.6 Design and development changes 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. ~~**The organization shall retain documented information on**~~: a) … b) – d) ~~**the**~~…	**8.3.6 Design and development changes** The organization shall **determine**, 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. **Documented information shall be available as evidence of:** a) … b) – d) …
8.4 Control of externally provided processes, products and services **8.4.1 General** … a) … b) products and services are provided directly to ~~**the customer(s)**~~ by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider ~~**as a result of a decision by the organization**~~ 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. ~~**The organization shall retain documented information**~~ of these activities and any necessary actions arising from the evaluations.	**8.4 Control of externally provided processes, products and services** **8.4.1 General** … a) … b) products and services are provided directly to **customers** by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider 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, products **or** services in accordance with requirements. **Documented information shall be available as evidence** of these activities and any necessary actions arising from the evaluations
8.4.2 Type and extent of control … a) ensure that externally provided processes ~~**remain**~~ within the control of its	**8.4.2 Type and extent of control** … a) ensure that externally provided processes **are** within the control of its quality

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quality management system; b)… c) take into ~~consideration~~: 1) – 2) … d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements	management system; b) … c) take into **account**: 1) – 2) … d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet **the** requirements
8.4.3 Information for external providers … The organization shall communicate to external providers its requirements for: a) – b) … c) competence, including any required qualification ~~of persons~~ d) the external providers' interactions with the organization e) control and monitoring ~~of the external providers' performance to be applied by the organization~~ f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises	**8.4.3 Information for external providers** … The organization shall communicate its requirements to external providers, **as appropriate**, for: a) – b) … c) competence, including any required qualification d) the external providers' interactions with the organization **and, as applicable, its customers and other relevant interested party** e) **the** control and monitoring **it applies to the performance of its external providers** f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises **or other location**
8.5 Production and service provision **8.5.1 Control of production and service provision** … Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products ~~to be produced, the~~ services ~~to be provided, or~~ the activities to be performed; 2) the results to be achieved; b) – h) …	**8.5 Production and service provision** **8.5.1 Control of production and service provision** … **The** controlled conditions shall include, as applicable: a) the availability **and use** of documented information that defines: 1) the characteristics of the products **or** services; 2) the activities to be performed; 3) the results to be achieved; b) – h) …
8.5.2 Identification and traceability The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. ~~The organization shall~~ identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. ~~The organization shall~~ control the unique identification of the outputs when traceability is a requirement, ~~and shall retain the~~ documented information necessary to enable traceability	**8.5.2 Identification and traceability** The organization shall: a) use suitable means to identify outputs when it is necessary to ensure the conformity of products and services; b) identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision c) control the unique identification of the outputs when traceability is a requirement d) **ensure that** documented information necessary to enable traceability **is available as evidence**.
8.5.3 Property belonging to customers or external providers …	**8.5.3 Property belonging to customers or external providers** …

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The organization shall identify, verify, protect and safeguard customers~~'~~ or external providers~~'~~ property provided for use or incorporation into the products and services. When the property ~~**of a**~~ customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider ~~**and retain**~~ documented information on what has occurred. NOTE ~~**A**~~ customer~~**'s**~~ or external provider~~**'s**~~ property can include materials, components, tools and equipment, premises, intellectual property and personal data.	The organization shall identify, verify, protect and safeguard property **belonging to** **customers** or external **providers** **that is** provided for use or incorporation into the products and services When the property **belonging to** 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. Documented information **shall be available as evidence of** what has occurred. NOTE Property **belonging to** customer or external provider can include materials, components, tools and equipment, premises, intellectual property and personal data.
8.5.4 Preservation	**8.5.4 Preservation** (без изменений)
8.5.5 Post-delivery activities	**8.5.5 Post-delivery activities** (без изменений)
8.5.6 Control of changes … 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.	**8.5.6 Control of changes** … Documented information shall **be available as evidence of** the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.
8.6 Release of products and services … ~~**The organization**~~ shall ~~**retain**~~ documented information ~~**on**~~ the release of products and services. The documented information shall include: a) – b) …	**8.6 Release of products and services** … Documented information shall **be available as evidence of** the release of products and services. The documented information shall include: a) – b) …
8.7 Control of nonconforming outputs **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. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. ~~**This shall also apply to nonconforming products and services**~~ detected after delivery of products, during or after the provision of services. … Conformity to the requirements shall ~~**be verified**~~ when nonconforming outputs are corrected. **8.7.2** The organization shall ~~**retain**~~ documented information that: a) ~~**describes**~~ the nonconformity; b) ~~**describes**~~ the actions taken; c) ~~**describes**~~ any concessions obtained; d) ~~**identifies**~~ the authority deciding the action in respect of the nonconformity	**8.7 Control of nonconforming outputs** **8.7.1** The organization shall ensure that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This **includes nonconformities** detected after **product delivery or during or after service provision**. … When nonconforming outputs are corrected **the organization** shall **verify** conformity to the requirements. **8.7.2** Documented information shall **be available as evidence of**: a) **the nature of** the nonconformity; b) the actions taken; c) any concessions obtained; d) the authority deciding the action in respect of the nonconformity

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9 Performance evaluation **9.1 Monitoring, measurement, analysis and evaluation** **9.1.1 General** … a) … b) the methods for monitoring, measurement, analysis and evaluation ~~**needed**~~ to ensure valid results. … ~~**The organization**~~ shall ~~**retain**~~ ~~**appropriate**~~ documented information as evidence of the results.	**9 Performance evaluation** **9.1 Monitoring, measurement, analysis and evaluation** **9.1.1 General** … a) … b) the methods for monitoring, measurement, analysis and evaluation, **as applicable**, to ensure valid results … Documented information shall **be available as evidence** of the results.
9.1.2 Customer satisfaction The organization shall monitor customer~~**s' perceptions of the degree to which their needs and expectations have been fulfilled**~~. The organization shall determine the methods for obtaining, monitoring and reviewing ~~**this**~~ information. 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.	**9.1.2 Customer satisfaction** The organization shall monitor customer satisfaction. The organization shall determine the methods for obtaining, monitoring and reviewing **customer satisfaction** information. NOTE **Source of information to support of customer satisfaction** can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, **complaints**, warranty claims, dealer reports **and social media**.
9.1.3 Analysis and evaluation … a) … b) ~~**the degree of**~~ customer satisfaction c) … d) ~~**if planning has been implemented effectively**~~; e) the effectiveness of actions taken to address risks ~~**and opportunities**~~ f) … g) … NOTE …	**9.1.3 Analysis and evaluation** … a) … b) customer satisfaction c) … d) **the effectiveness of planning implementation** e) the effectiveness of actions taken to address risks f) the effectiveness of actions taken to address opportunities g) … h) … NOTE …
9.2 Internal audit **9.2.1** … **9.2.2** The organization shall: 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;	**9.2 Internal audit** **9.2.1 General** … **9.2.2 Internal audit programme** The organization shall plan, establish, implement and maintain **(an)** audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting. **When establishing the internal audit programme(s) the organization** shall **consider** the importance of the processes concerned and the results of previous

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  b) define the audit criteria and scope for each audit; c) – e) … f) ~~**retain**~~ documented information as evidence of the implementation of the audit programme and the audit results. NOTE See **ISO 19011** for guidance	audits and changes affecting the organization. The organization shall: a) define the audit **objectives**, criteria and scope for each audit; b) – d) … Documented information shall **be available as evidence** of the implementation of the audit programme**(s)** and the audit results. NOTE See **[5]** for guidance **on auditing management systems**
9.3 Management review **9.3.1 General**	**9.3 Management review** **9.3.1 General** (без изменений)
9.3.2 Management review inputs The management review shall ~~**be planned and carried out taking into consideration**~~: a) – b) … c) information on ~~**the**~~ performance ~~**and effectiveness of**~~ the quality management system, including trends in: 1) - 3)… 4) – 6)… 7) … d) … e) the effectiveness of actions taken to address risks ~~**and opportunities (see 6.1)**~~ f) opportunities ~~**for improvement**~~	**9.3.2 Management review inputs** The management review shall **include**: a) – b) … c) **changes in needs and expectation of interested parties that are relevant to the quality management system** d) information on the quality management system performance, including trends in: 4) – 6) … 1) – 3) … 7) … f) … g) the effectiveness of actions taken to address risks (see **6.1.2**) h) **the effectiveness of actions taken to address** opportunities **(see 6.1.3)**
9.3.3 Management review outputs The outputs of the management review shall include decisions and actions related to: 1) opportunities for improvement 2) any need for changes to the quality management system 3) resource needs. The organization shall ~~**retain**~~ documented information as evidence of the results of management reviews.	**9.3.3 Management review results** **The results of the management review shall include decisions related to improvement opportunities and any need for changes to the quality management system and resource needs**. Documented information shall **be available as evidence** of the results of management reviews.
10 Improvement **10.1 General** The organization shall ~~**determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction**~~.	**10 Improvement** **10.1 Continual improvement** The organization shall **continually improve the suitability, adequacy and effectiveness of the quality management system**. **The organization shall consider the results of monitoring, measurement, analyses and evaluation of data and information and the results of**

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~~These~~ shall include: a) improving products and services ~~to meet requirements as well as to address future needs and expectations~~; b) … c) ~~improving the performance and effectiveness of the quality management system~~. NOTE ~~Examples of~~ improvement ~~can include correction, corrective action, continual improvement~~, breakthrough change, innovation and re-organization.	**management review, to determine opportunities. The organization shall address these opportunities as part of continual improvement.** **Actions** shall include: a) improving **processes**, products and services; b) **addressing future needs and expectations**; c) … NOTE Improvement can **be achieved through incremental or** breakthrough change, innovation and reorganization **initiatives**.
10.2 Nonconformity and corrective action **10.2.1** When a nonconformity occurs~~, including any arising from complaints,~~ the organization shall: a) … b) … 1) reviewing ~~and analysing~~ the nonconformity 2) … 3) determining if similar nonconformities exist, or ~~could~~ potentially occur c) – f) … …	**10.2 Nonconformity and corrective action** **10.2.1** When a nonconformity occurs the organization shall: a) … b) … 1) reviewing the nonconformity 2) … 3) determining if similar nonconformities exist, or **can** potentially occur c) – f) … …
10.2.2 ~~The organization~~ shall ~~retain~~ documented information as evidence of: a) - b) ...	**10.2.2** Documented information shall **be available** as evidence of : a) - b) ...
~~**10.3 Continual improvement**~~ ~~**The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.**~~ ~~**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.**~~	(раздел исключён)

Изменения в структуре Приложения А

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A.1 Structure and terminology **A.2 Products and services** **A.3 Understanding the needs and expectations of interested parties** **A.4 Risk-based thinking** **A.5 Applicability** **A.6 Documented information**	**A.1 General** **A.2 Structure and terminology** **A.3 Applicability** **A.4 Context of organization** **A.4.1 Understanding the organization and its context** **A.4.2 Understanding the needs and expectations of interested parties**

A.7 Organizational knowledge **A.8 Control of externally provided processes, products and services**	**A.4.3 Determining the scope of the quality management system** **A.4.4 Quality management system and its processes** **A.5 Leadership** **A.5.1 Leadership and commitment** **A.5.2 Quality policy** **A.5.3 Organizational roles, responsibilities and authorities** **A.6 Planning** **A.6.1 Actions to address risks and opportunities** **A.6.1.1 General** **A.6.1.2 Risk-based thinking** **A.6.1.3 Opportunity-based thinking** **A.6.2 Quality objectives and planning to achieve them** **A.6.3 Planning of changes** **A.7 Support** **A.7.1 Resources** **A.7.1.1 General** **A.7.1.2 People** **A.7.1.3 Infrastructure** **A.7.1.4 Environment for the operation of processes** **A.7.1.5 Monitoring and measuring resources** **A.7.1.6 Organizational knowledge** **A.7.2 Competence** **A.7.3 Awareness** **A.7.4 Communication** **A.7.5 Documented information** **A.8 Operation** **A.8.1 Operational planning and control** **A.8.2 Requirements for products and services** **A.8.3 Design and development of products and services** **A.8.4 Control of externally provided processes, products and services** **A.8.5 Production and service provision** **A.8.6 Release of products and services** **A.8.7 Control of nonconforming outputs** **A.9 Performance evaluation** **A.9.1 Monitoring, measurement, analysis and evaluation** **A.9.2 Internal audit** **A.9.3 Management review** **A.10 Improvement** **A.10.1 Continual improvement** **A.10.2 Nonconformity and corrective action**