

# Intent of AS9100 Paragraphs

## **4 Context of the organization**

### **4.1 Understanding the organization and its context**

Maintain awareness of the external and internal issues relevant to the organization's setting that can impact its ability to achieve intended QMS results.

### **4.2 Understanding the needs and expectations of interested parties**

Maintain awareness of the requirements of relevant interested parties ((customer, statutory, regulatory, etc.), that can impact the organization's ability to deliver outcomes.

### **4.3 Determining the scope of the quality management system**

Given the organization context, determine what parts of the Standard are applicable.

### **4.4 Quality management system and its processes**

Define and communicate the processes needed for the QMS and how they are applied in the Plan-Do-Check-Act cycle.

## **5 Leadership**

### **5.1 Leadership and commitment**

Demonstrate that the highest level of management is actively engaged in and accountable for the effectiveness of the QMS throughout all aspects of the PDCA cycle, including a focus on meeting all requirements (customer, statutory, regulatory) while considering risks, opportunities and improvement of customer satisfaction.

### **5.2 Policy**

Create and communicate a quality policy statement that sets the vision and framework for the QMS.

### **5.3 Organizational roles, responsibilities and authorities**

Ensure roles, responsibilities and authorities are defined with QMS effectiveness measured and communicated.

## **6 Planning**

### **6.1 Actions to address risks and opportunities**

Determine and take effective action on the risks and opportunities that need to be addressed in order to deliver desired outcomes, prevent or reduce undesired occurrences and continually improve.

### **6.2 Quality objectives and planning to achieve them**

Establish, communicate and maintain measurable objectives for relevant QMS functions, levels and processes.

### **6.3 Planning of changes**

Plan and systematically implement any changes to the QMS in a way that addresses risk and resources while preserving its integrity.

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## **7 Support**

### **7.1 Resources**

Determine and provide the internal and external resources needed for the effective operation of the QMS to ensure customer, statutory, regulatory requirements are met. Resources include: people, infrastructure, working environment, monitoring and measuring resources and organizational knowledge.

### **7.2 Competence**

Determine, ensure and where needed, acquire the necessary competence for people performing work affecting quality

### **7.3 Awareness**

Make sure all people working under the organization's control are aware of the quality policy and objectives and how their work impacts the effectiveness of the QMS, including risks and benefits. Ensure awareness of: documented info and changes, contribution to product/service conformity and product safety, importance of ethical behavior.

### **7.4 Communication**

Maintain a plan for internal and external communications related to the QMS, including feedback from internal and external sources.

### **7.5 Documented information**

To maintain accurate, up-to-date and accessible information necessary for effective operation of the QMS and retention of evidence of compliance to requirements.

## **8 Operation**

### **8.1 Operational planning and control**

Establish and control the processes needed for product/service provision (including planned changes to them). Manage: risks related to operational processes, product configuration, product safety and prevention of counterfeit parts.

### **8.2 Requirements for products and services**

Ensure customer requirements (along with changes and contingency actions) are understood, complete, reviewed and achievable.

### **8.3 Design and development of products and services**

Maintain a controlled design and development process in order to: design products/services that meet customer requirements, maintain change control, enable correct production/provision of products and services, ensure offerings are fit for safe and proper intended use.

### **8.4 Control of externally provided processes, products and services**

Ensure purchases are obtained from approved providers and meet requirements. Identify risks related to external provision, establish appropriate controls, provide accurate information to providers and evaluate their performance.

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## **8.5 Production and service provision**

Control the conditions for producing and/or providing products/services, including post-delivery activities, through the use of appropriate supporting processes and resources (per section 7). Control and preserve the inputs to and outputs of production/service provision processes to maintain configuration, safety and conformance. Validate, verify and control changes to processes, equipment, tools and software as appropriate to ensure conformance of products/services.

## **8.6 Release of products and services**

Implement planned verification steps (checks, inspections, tests, certifications, etc.) and ensure proper authorization and record keeping before releasing products/services to the customer.

## **8.7 Control of nonconforming outputs**

Ensure that any products, services and/or their constituent parts that do not meet requirements are controlled in order to prevent unauthorized use, whether before or after release to the customer.

## **9 Performance evaluation**

### **9.1 Monitoring, measurement, analysis and evaluation**

Establish monitoring and measurement within the QMS, analyze collected data and use this information to evaluate the quality of products/services, the level of customer satisfaction and the effectiveness of the QMS, and identify improvement needs/opportunities.

### **9.2 Internal audit**

Establish an audit program to examine whether all requirements of the QMS are being met and whether it is effectively implemented and maintained.

### **9.3 Management review**

Engage top management in periodic assessment of the suitability, adequacy and effectiveness of the QMS using information gained through analysis and evaluation, and considering changes in organization context or strategic direction.

## **10 Improvement**

### **10.1 General**

Identify and act on improvement opportunities in order to prevent future nonconformities, continue to meet current and predicted customer requirements and improve QMS results.

### **10.2 Nonconformity and corrective action**

Contain nonconformities when they happen and evaluate whether further action to eliminate their root causes is warranted. When corrective action is required, track actions and effectiveness of results.

### **10.3 Continual improvement**

Use all outputs of analysis and evaluation, including management review, to determine needs or opportunities to be addressed as part of continual improvement of the suitability, adequacy and effectiveness of the QMS.