

AS 9100:2016 REV D

Awareness

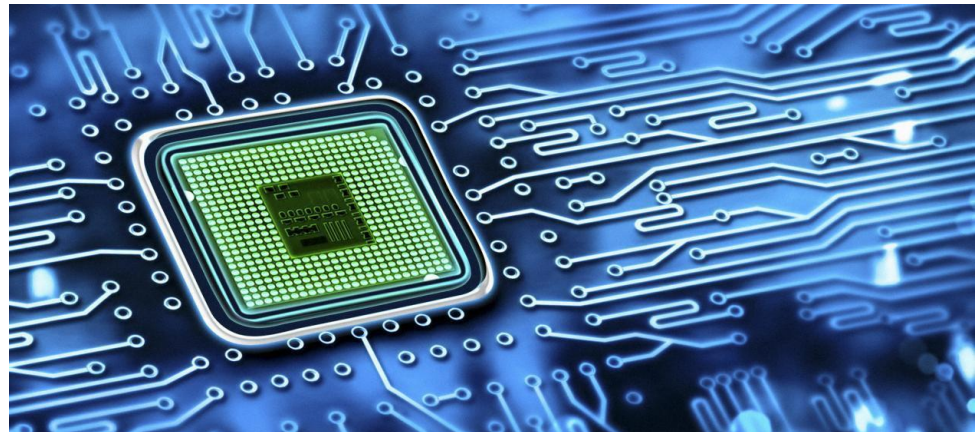
TRAINING

Kelsey Casto

Instructor

2020

Tekmos, Inc.

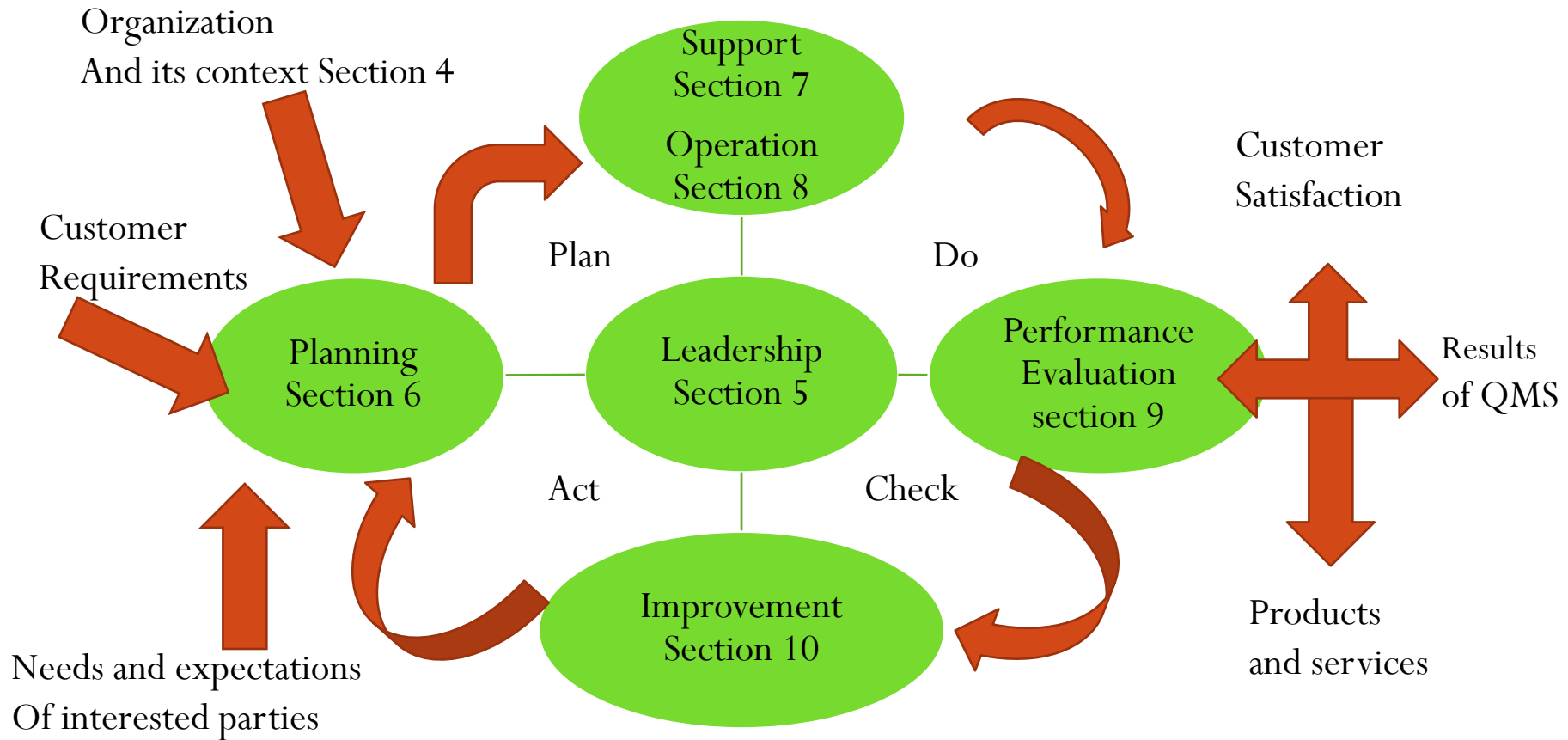


Quality Policy

Our goal is to provide customer support for existing and newer technologies, deliver reliable product and exceed customer expectations. We will have continual quality improvement while building relations with our suppliers to ensure product integrity.

We will provide high reliability products to military, aerospace, medical, industrial, oil and related industries while positioning the company for future growth.

QMS mapped to Plan Do Check Act (PDCA) Cycle



7 Quality Management Principles

Customer Focus :

- primary focus of a QMS meets requirements and expectations of customers and interested parties.
- By sustainable business success for long-term growth.
- Every customer interaction strengthens relationships.

Leadership:

- Exemplifies importance of QMS
- communicates why adherence to the associated policies and procedures are critical to the success of the organization.

Engagement of People:

- Individuals at each level of the organization must understand how their role and job function contribute to the achievement of business objectives and business success.

Process Approach:

- A disciplined and consistent approach to its processes ensures stability. This stability allows the organization to measure their performance to determine if they are operating in an effective and efficient manner.

Improvement:

- World-class organizations are constantly striving for any type of improvement. This is an iterative process.

Evidence-based decision-making:

- Business decisions are made on evidence-based data collection metrics.

Relationship Management:

- No organization exists or operates in a vacuum. They must forge constructive relationships with each of their interested parties in order to maintain customer focus and ensure continuity of supply for their operations

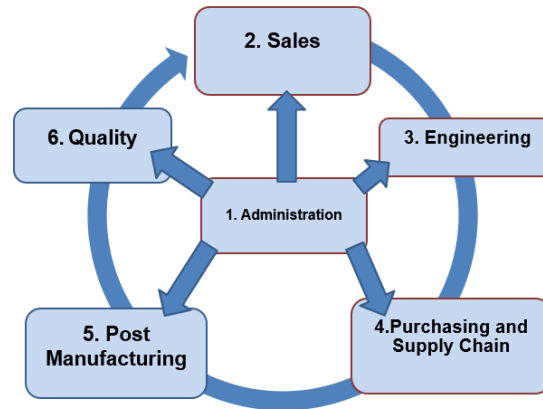
Interested Parties

- Stakeholders
- Employees
- Customers
- Vendors/Suppliers
- Regulatory/Certified Body

Tekmos shall satisfy the needs of all interested parties affected by company product and services.

Tekmos Core Processes:

Administrative, Sales, Engineering, Purchasing and Supply Chain, Post Manufacturing, Quality



- These processes will be audited starting with a **process owner**, **process objectives** and **interactions** with other processes in the system
- Samples will be taken to measure inputs, activities, outputs.
- Using this information, a decision of effectiveness of the processes to meet the intended outcomes will be evaluated

Key Process Indicators (KPI)

- KPIs are a measurable value that demonstrates how effectively a company is achieving **key** business objectives
- Below are Tekmos' KPIs for each Core Process

- **Administrative**

- Employee Performance Evaluations (annually)

- Customer Satisfaction Yearly Survey Responses (every 3rd Quarter)

- IT: # of days network has not had issues

- **Sales**

- Response time for inquires/ Quarter

- # of Quote/ Quarter

- **Engineering**

- # of failed designs/ Quarter

- **Purchasing and Supply Chain**

- # of Supplier Nonconformances/ Quarter

- # of Supplier Late Deliveries/ Quarter

- Assembly Instruction Delivery/ Quarter

- **Post Manufacturing**

- # of not met shipments / quarter

- # of revised ship dates / quarter

- Cycle time to Finished Goods

- **Quality**

- #of NCP RMA/Quarter

- CAR timeliness

Example of Tekmos Risk Register

Process	Interested Party	Potential Risks	RATINGS				Class	Owner	Mitigation Program	Residual risk after mitigation
			Imp	Prob	Res	Score				
Strategic Risks								Lynn		
	Stakeholder, Customer, Company, Regulatory	Not properly assessing customer Flow Downs	3	3	1	7	Medium Risk	Not Required		
	Stakeholder, Customer, Company	Not staying ahead of product subject to phase out in the obsolete market	3	2	2	7	Medium Risk			
	Stakeholder	Failure to grow	3	3	3	9	Medium Risk			
	Employee, Company	Failure to properly succession plan	4	5	3	12	Significant Risk			
	Employee, Company	Unexpected Rapid Growth	2	1	4	7	Medium Risk			
	Stakeholder	Market opportunities with changing economic fluctuations	4	2	3	9	Medium Risk			
Administrative Process								Carole, Kelsey		
	Employee, Company	Failure to Maintain Documentation	1	1	1	3	Low Risk			
	Employee	Untrained Employee	3	1	1	5	Low Risk			
	Stakeholders	Ineffective KPI	2	1	1	4	Low Risk			
	Stakeholders	Ineffective Disaster Recovery	4	1	4	9	Medium Risk			
	All	Loss of Electronic Media	5	1	2	8	Medium Risk			
	Company	Lack of Change Control	2	1	1	4	Low Risk			
Sale Process								Bob		
	Stakeholder/Customer	Lack of Sales Opportunities	3	2	1	6	Medium Risk			
	Stakeholder/Customer	Failure to Support Customer Request	3	1	2	6	Medium Risk			
	Stakeholder/Customer	Ineffective Marketing	2	2	1	5	Low Risk			
	Stakeholder/Customer	Lack of new product to sale	2	3	1	6	Medium Risk			
	Stakeholder/Customer	Lack of high revenue design wins	3	3	1	7	Medium Risk			
	Customer	Not meeting schedules	2	4	1	7	Medium Risk			
Engineering Process								Lynn		
	Employee/Customer	Limited Tools	1	3	2	6	Medium Risk			
	Employee/Customer	Lack of experienced Analog Engineers	1	3	1	5	Low Risk			
	Employee/Customer	Lack of Test Engineering Resources	1	3	1	5	Low Risk			
	Employee	Poor Documentation Control	1	4	1	6	Medium Risk			
	Customer/Employee	Poor Design Verification	2	3	2	7	Medium Risk			
	Employee	Miscommunication between Engineers	1	3	1	5	Low Risk			
Purchasing-Supply Chain Process								Alison		
	Stakeholder/Supplier/Company	Supplier Stability	2	1	1	4	Low Risk			
	Stakeholder/Supplier/Company	Miscommunicated Work instructions	2	2	1	5	Low Risk			
	Stakeholder/Supplier/Company	Supplier Nonconforming Material	4	2	3	9	Medium Risk			
	Stakeholder/Supplier/Company	Delayed Supplier Delivery	4	3	1	8	Medium Risk			
	Stakeholder/Supplier/Company/Customer	Loss of Assembly Houses	4	2	3	9	Medium Risk			
	Stakeholder/Supplier/Company	Premature Design Approval	3	1	3	7	Medium Risk			
Post Manufacturing Process								Adrian		
	Stakeholder/Customer	Nonconforming product	4	3	3	10	Medium Risk	Jon, Kelsey		
	Stakeholder/Customer	Late/delayed delivery	2	3	1	6	Medium Risk			
	Employee and Customer	Machine malfunction	2	1	2	5	Low Risk			
	Employee and Customer	Miscommunicated work instructions	3	3	1	7	Medium Risk			
	Employee, Customers, Stakeholder	Tester Company going out of business	2	2	3	7	Medium Risk			
	Stakeholder/Customer	undertrained operators/ Lack of workforce	3	1	1	5	Low Risk			
Quality Process								Kelsey		
	Stakeholder/Customer	Nonconforming Product	4	3	3	10	Medium Risk	Jon, Kelsey		
	Customer	Unsatisfied Customers	2	3	1	6	Medium Risk			
	Employee	Uncontrolled Documents	1	1	1	3	Low Risk			
	Employee/Customer	Ineffective Audits	1	1	1	3	Low Risk			
	Stakeholder/Employee	Uncommunicated employee Quality Roles	1	1	1	3	Low Risk			

Contribution to Product or Service Conformity

Administrative: Employee Training and Oversight on Service and Product Conformity

Employee's are trained to meet all customer requirements regarding products and services, while management monitors adherence to KPI (Key Process Indicators) metrics.

Sales: Customer Service and Product Requirement Flow Downs

Customer requests are handled with on time customer communication, and all related requirements are flowed down to appropriate personnel in order to deliver correct, and on time product.

Engineering: Technical Inquiries Service and Product Design Conformity

Product designs meet customer requirements and any technical request regarding design are prompt and clear.

Purchasing and Supply Chain: On Time Delivery Projection Service and Product Manufacturing Conformity

Order conforming material's that meet customer specifications while meeting projected delivery timelines.

Post Manufacturing: On Time Delivery Service and Product Conformity Verification

100% test of all product to meet customer design specifications, and agreed to delivery dates.

Quality: Ensures Conformity of Product and Services Through Related Processes and Procedures

Monitors processes and procedures to accomplish effective and efficient methods used to produce products and services.

All Processes' contribution to the Quality Management System will help against potential product safety issues.

External Document Control

- AS9100 states that “all documented information of external origin determined by the organization to be necessary for the planning and operations of the quality management system shall be identified as appropriate, and be controlled”
- Why?- This will provide Tekmos one location that employees may search through to find any external document needed for their job.
- Owner is responsible for coordinating with Quality to ensure that the documents are current and accurate.
- DL02 External Document Log can be found in- Quality Drive / 6) Quality / External Document Index

Ethical Behavior



Review of QMS Clauses



Context of Organization

AS9100 RevD Clause 4



- Understanding the organization and its content
- Understanding the needs and expectations of interested parties
- Determining the scope of the quality management system
- Quality Management system and its processes

Leadership

AS9100 RevD Clause 5

- Leadership and commitment
- Quality Policy
- Organizational roles, responsibilities and authorities



Planning for the QMS

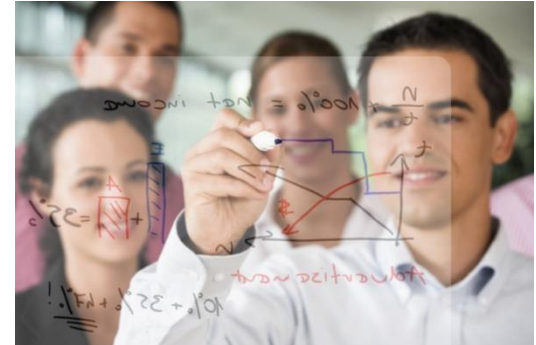
AS9100 RevD Clause 6

- Planning the QMS
- Actions to address Risks and Opportunities
- Quality Objectives and planning to achieve them
- Planning of changes

Support

AS9100 RevD Clause 7

- Resources
- Competence
- Awareness
- Communication
- Documented information



Operation

AS9100 RevD Clause 8



Operational Planning and control (8.1)

Determination of customer requirements (8.2)

Design and Development (8.3)

External Provisions(Purchasing) (8.4)

Control of Production/Service (8.5)

Release of Product and Services (8.6)

Control of nonconforming process outputs, products/services (8.7)

Similar to ISO 9001:2008, but the key change is linking the activities to address risks and opportunities from Clause 6 Planning.

The expansion of the purchasing clause to include control of externally provided processes, products and services,

The introduction of a clause to address control of changes.

Performance Evaluation

AS9100 RevD Clause 9

- Customer satisfaction
- Internal Audit
- Management Review

Improvement

AS9100 RevD Clause 10

- Nonconformity and corrective action
- Continual Improvement

Implications of not conforming to the Quality Management System

Internal Nonconformances

- Employees and Processes not conforming to the Quality Management system will receive a Corrective Action Request (CAR) to correct the non-conformances.

Supplier Nonconformances

- Suppliers not conforming to Tekmos requirements will receive a Supplier Corrective Action Request (SCAR) and/or be removed as an approved supplier.

Audit Nonconformances

- Nonconformances found in Certification Audits could lead to a CAR or removal of the AS9100 Tekmos Certification.
- Nonconformances found in Customer Audits could lead to CAR or loss of future business.

Material Nonconformances

- Nonconforming material sent to customers could lead to Product Safety issues, loss of future business, and Returned Material.