D 21v16

AS9100D readiness version 2016

Goal

Goal of the module: Readiness for implementation, certification, maintenance and improvement of your aerospace quality management system AS9100D in order to:

- increase the satisfaction of interested parties
- improve your overall performance
- seize opportunities for continual improvement

1 Quality approach

1.1 Background

Quality management system (QMS) standards emerged in the 1980s:

- 1987: ISO 9000 first edition: ISO 9001; ISO 9002; ISO 9003; ISO 9004
- 1994: ISO 9000 revision 1: ISO 9001; ISO 9002; ISO 9003; ISO 9004 - more comprehensible, better defined customer focus, addition of preventive actions
- 2000: ISO 9000 revision 2: ISO 9000; ISO 9001; ISO 9004 - simplified structure (8 clauses), process approach and customer satisfaction priority
- 2008: revision No. 3 (fourth edition of ISO 9001): clarifications of requirements (no new requirements), better consistency with ISO 14001
- 2015: revision No. 4: new structure (higher level), addition of risks, performance becomes priority, lightened documentation

Aerospace references appeared in the 1990s:

- RG Aéro 000 83 (1994) (Qualifas Association - Supply Quality for the French Aerospace and Space Industries)
- ARD9000 (1996) - Aerospace Basic Quality System Standard
- D1-9000 (1997) - Advanced Quality System (Boeing)
- AS9000 (1997) - Aerospace Basic Quality System Standard
- AS9100 (1999) - Quality management systems requirements and Quality systems
- EN 9100 (2003) - Requirements (based on ISO 9001: 2000) and quality system. Model for quality assurance in design, development, production, installation and operation (based on ISO 9001: 1994)
- EN 9100 (2010): Aerospace Series - Quality Management Systems - Requirements for Aeronautics, Space and Defense Organizations
- AS9100D (2016) - Quality Management Systems - Requirements for Aviation, Space, and Defense Organizations

The ISO 9000 standards have appeared in:

- 1987: first edition
- 1994: first revision, more understandable, customer focus better determined, preventive actions added
- 2000: second revision, simplified structure (8 clauses), priority to process approach and customer satisfaction
- 2008: third revision, clarification of the requirements (no new requirement), better alignment with ISO 14001
- 2015: fourth revision, new structure (high level), added risk-based thinking, performance becomes a priority, lightweight documentation

The first version of the AS9100 standard was published in 1999 under the direction of SAE (Society of Automotive Engineers) and AECMA (European Association of Aerospace Material Manufacturers) now ASD - AeroSpace and Defense Industries Association of Europe. The AS9100 standard (EN 9100 for Europe, first edition in 2003) is globally accepted by all participants in the aerospace industry.

The role of the International Aerospace Quality Group (IAQG) and the European Aerospace Quality Group (EAQG) was essential to replacing existing standards in different countries with a single standard.

The latest version of the standard (AS9100D, version 2016) was published by the SAE.

1.2 Scope

The AS9100D standard applies to any civilian or military company (regardless of size) that manufactures aerospace products in the area of design, development, production and related services. Companies mainly supplying maintenance services use the EN 9110 standard and those in distribution use the EN 9120 standard.

This allows a unique certification recognized worldwide for any company related to aerospace production. The requirements of the AS9100D and the specific requirements of customers are the basis of any management system for manufacturers in the aerospace field.

Certain requirements of the standard may not apply to the aerospace quality management system (see sub-clause 4.3).

1.3 Principles and steps

Quality is anything that can be improved. Masaaki Imai

The quality approach is a state of mind which starts with top management as a priority strategic decision and extends to all employees. Top management develops a quality policy which determines the quality objectives, themselves applicable to all activities. The tool used to achieve the objectives is the aerospace quality management system. Prevention is a key concept of quality management systems.

The aerospace quality management system includes three distinct and interrelated steps:

- the process approach
- risk-based thinking
- continual improvement

The purpose of an aerospace quality management system is to increase the satisfaction of customers (both external and internal) by meeting their needs and expectations through continual improvement of the effectiveness of the processes.

Quality is almost free when customers are satisfied: they remain loyal to us. It’s only when the customer is not fully satisfied that quality becomes very expensive to us: sooner or later the customer will go to a competitor.

Quality remains long after the price has been forgotten

The seven quality management principles (cf. figure 1-1) will help us achieve sustained success (cf. ISO 9000: 2015, sub-clause 2.3). Previously there were eight principles but now the system approach is integrated into the process approach.

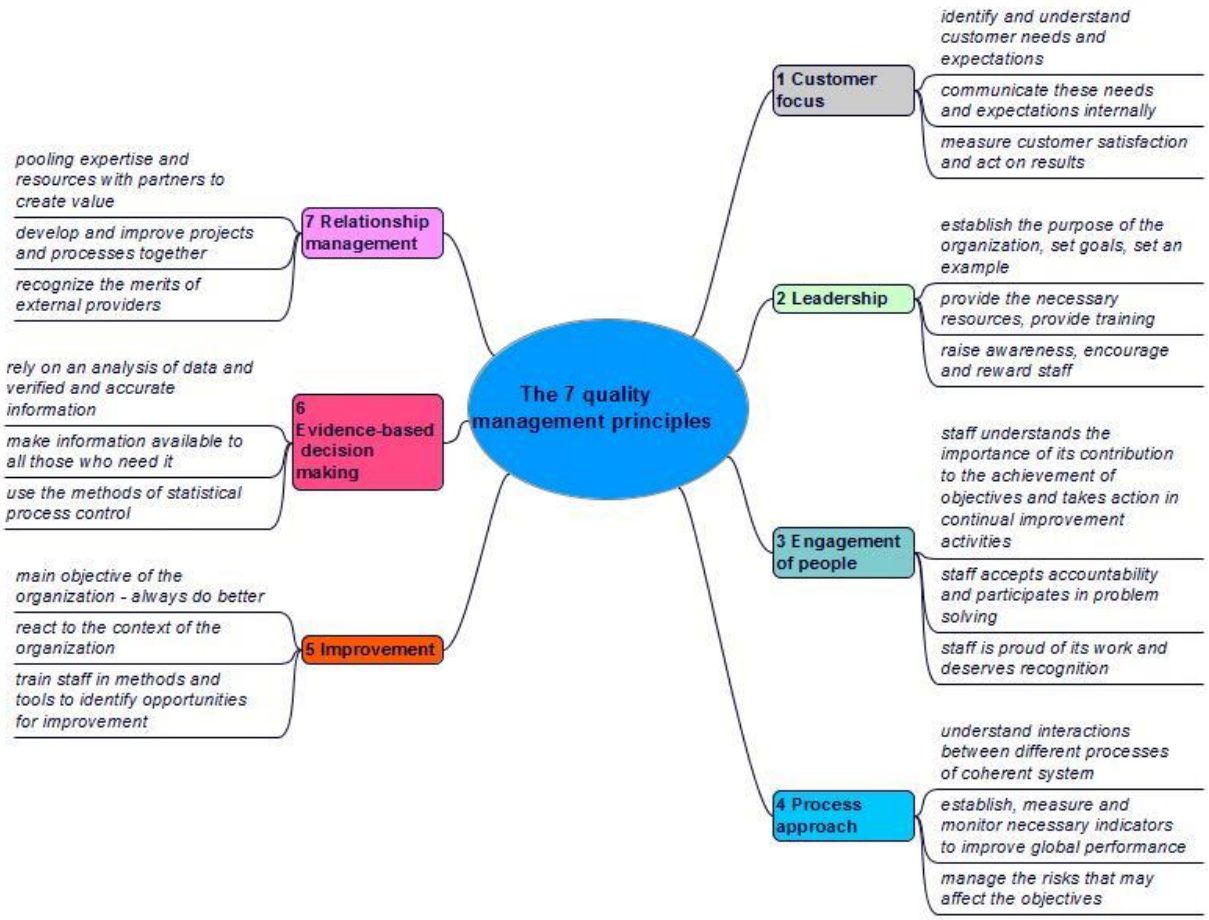


Figure 1-1. The 7 quality management principles

A well-prepared approach is halfway to success

The approach to implementing an aerospace quality management system (AQMS) starts with preparation. An example is shown in figure 1-2.

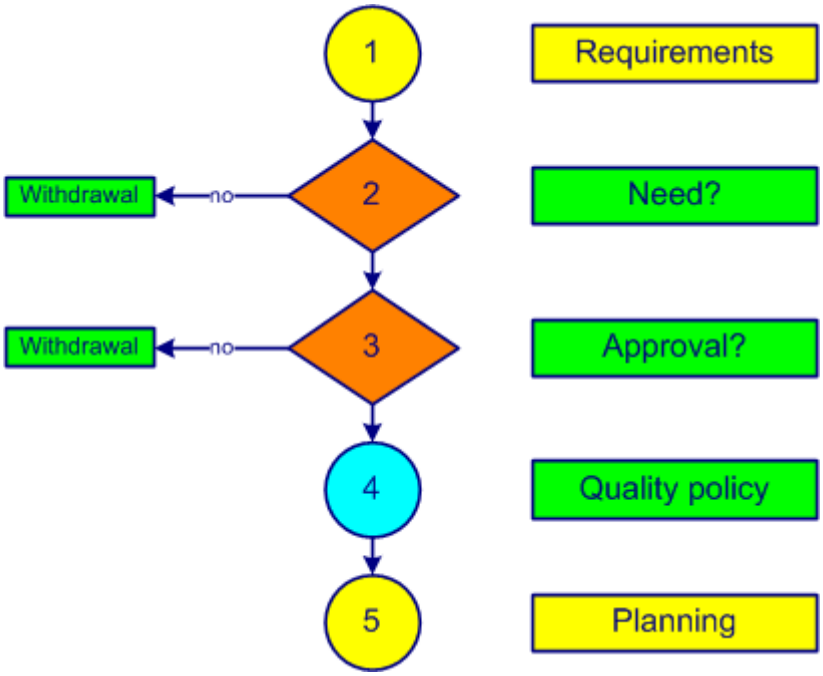


Figure 1-2. AQMS preparation

Step 1 involves identifying the needs and expectations (**requirements**) of interested parties:

- staff
- customers, distributors and consumers
- competitors
- shareholders and investors
- external providers (suppliers, subcontractors and partners)
- organizations and branch associations
- statutory and regulatory authorities

The involvement of top management at its highest level is truly indispensable. The advice of a consultant is often solicited. A mandatory prerequisite is the ISO 9001 version 2015 certification. Choose an external certification body (it may be different from that for ISO 9001).

One of the key questions which comes up quickly (**step 2**) is the **need** for this decision. If this is not really necessary or if the estimated costs of the certification approach exceed the available resources, it is better to reject this idea immediately.

The ISO 9000 family of standards will stop you making promises you can't fulfil and help you keep those you can. David Hoyle

The benefits of implementing a quality management system are often:

- an improved image of the company
- being one step ahead of the competition
- enhanced customer satisfaction
- better economic results
- increased daily effectiveness
- staff who are aware, consulted, motivated and proud
- high level of risk control
- reduced insurance costs

- profitable engagement for all
- best practices are valorized
- formalization of knowledge
- process control
- updated legal obligations

The benefits of the certification of a quality management system are often:

- new customers
- increased market share
- an increase in sales
- better financial performance

More than one and a half million businesses worldwide cannot be wrong!

The internalization of the spirit of the principles and requirements of an ISO standard significantly improves the overall performance of your business, especially when it is not considered as a constraint.

The **third step** shall determine whether this approach receives the **approval** of the staff. A communication campaign is launched in-house on the objectives of an aerospace quality management system (AQMS). The staff is aware and understands that, without their participation, the project cannot succeed.

Have confidence: success will come with the involvement and effort of all!

The vision (what we want to be), the mission (why we exist) and the strategic direction of the company are determined. The **following step** (**4**) includes adding specific aerospace requirements in the **quality policy.** If you do not have a copy of the AS9100D standard, now is the time to get it (cf. sub-clause 2.1 of the present module).

Planning is the last **step** (**5**) of the project preparation for obtaining AS9100D certification. A reasonable period is between 5 to 8 months (each company is unique and specific). The financial resources and staff are confirmed by top management. A management representative (usually it is the quality manager) is appointed as project leader. Top management commitment is formalized in a document communicated to all staff.

The establishment and implementation of an aerospace quality management system are shown in figure 1-3.

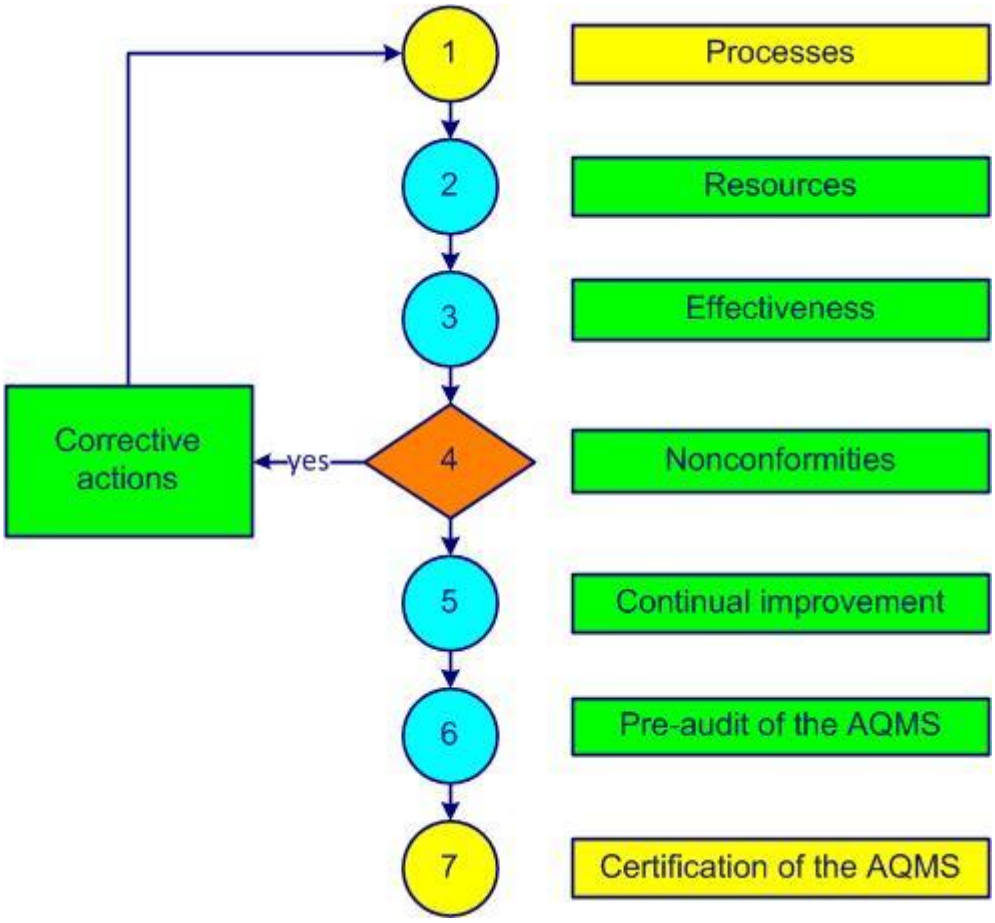


Figure 1-3. AQMS implementation

Step 1 aims to identify and determine the specific aerospace requirements in **processes** and documented information. New documented information is created (FMEA, quality plan). The quality manual is updated.

In **Step 2** the new necessary **resources** to achieve the quality objectives are set. Planning tasks, responsibilities and time frames are established. Training of internal auditors to aerospace requirements is taken into account.

Step 3 allows you to set and implement methods for measuring the **effectiveness** and efficiency of each process. Internal audits help to evaluate the degree of implementation of specific requirements.

Nonconformities of all kinds are listed in **Step 4**. A first draft for dealing with waste is established. Corrective actions are implemented and documented.

A first encounter with the tools and application areas of **continual improvement** is made in **step 5**. A table with the main costs of obtaining quality (COQ) is filled in by those with the information at hand. Risks are determined, actions are planned and opportunities for improvement are found. An approach to preventing nonconformities and eliminating causes is established. The internal and external communication is established and formalized.

To conduct the **pre-audit of the AQMS** (**Step 6**), documented information is checked and approved by the appropriate people. A management review allows evaluation of compliance with applicable requirements. The quality policy and objectives are finalized. A quality manager from another company or a consultant can provide valuable feedback, suggestions and recommendations.

When the system is accurately implemented and followed, the **certification of the AQMS** by an external body is a breeze, a formality (**step 7**).

An example of a certification project plan with 26 steps is shown in annex 01.

An appropriate method for evaluating the performance of your quality management system is the RADAR logic model of excellence EFQM (European Foundation for Quality Management), with its 9 criteria and overall score of 1000 points.

The Deming cycle (figure 1-4) is applied to control any process. The PDCA cycles (Plan, Do, Check, Act) are a universal base for continual improvement.

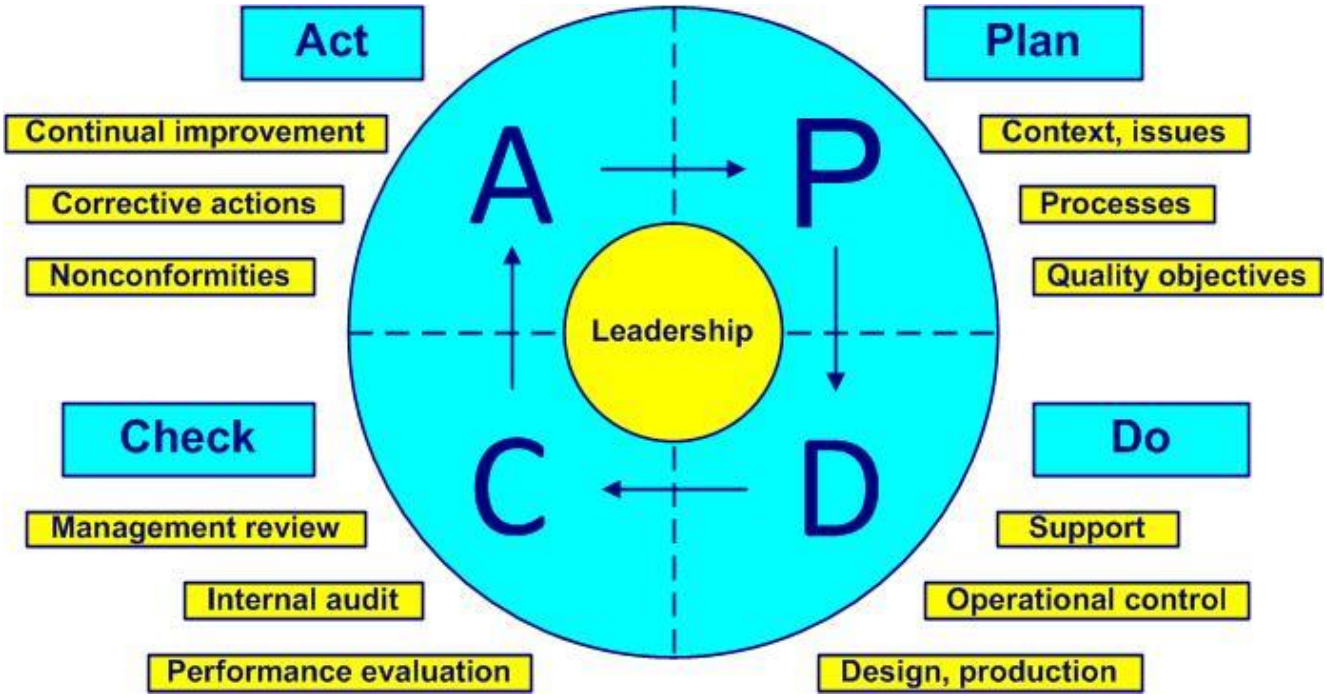


Figure 1-4. The Deming cycle

- Plan – define context, issues and processes, demonstrate leadership, establish quality policy and objectives (clauses 4, 5 and 6)
- Do – realize the product, develop, implement and control processes, demonstrate leadership and bring support (clauses 5, 7 et 8)
- Check – compare, evaluate, inspect, analyze data, conduct audits and management reviews and demonstrate leadership (clauses 5 and 9)
- Act – adapt, demonstrate leadership, treat nonconformities, react with corrective actions and find new improvements (new PDCA cycle), (clauses 5 and 10)

For more information on the Deming cycle and its 14 points of management theory (cf. table 1-1), you can consult the classic book "Out of the crisis" (W. Edwards Deming, MIT press, 1982).

Table 1-1. The 14 Deming points

Points	Description
1	Create constancy of purpose for permanent improvement of products and services, in order to become competitive, stay in business and provide jobs
2	Adopt the new philosophy in the new economic age. Western management must accept its responsibilities and lead for change

3	Don't be dependent on inspection to achieve quality. Eliminate mass inspection by including quality in the product in the first place
4	Stop buying just on the basis of a low price. Minimize further total costs by cutting down the number of suppliers and build long-term relationships of loyalty and trust with them
5	Improve the production system permanently, improve quality and productivity to obtain costs decrease
6	Establish training for all
7	Establish leadership. The purpose of supervision is to help people, equipment and tooling to do a better job
8	Keep fear out of sight: everybody's work will be more efficient
9	Break down barriers between departments. Teamwork is needed throughout the whole organization to foresee potential problems
10	Eliminate slogans and targets asking for zero defects from the work force. Most of the causes of low quality and productivity belong to the system
11	a. Eliminate work quotas on the shop floor. Substitute leadership b. Eliminate management by objectives. Eliminate management by numerical goals. Substitute leadership
12	a. Remove barriers that rob the worker of the pride of their workmanship b. Remove barriers that rob the people in management of the pride of their workmanship
13	Establish a vigorous training and self-improvement program
14	Put everybody to work to accomplish the transformation. It's everybody's job

2 Standards, definitions, books

2.1 Standards

The ISO 9000 family of standards contains three core booklets (and one guidelines):

- ISO 9000 (2015): Quality management systems - Fundamentals and vocabulary
- ISO 9001 (2015): Quality management systems - Requirements
- ISO/TS 9002 (2016): Quality management systems - Guidelines for the application of ISO 9001:2015
- ISO 9004 (2018): Quality management - Quality of an organization - Guidance to achieve sustained success

The AS9100 family mainly includes the following standards:

- AS9102B (2014): Aerospace Series - Quality Systems – Aerospace First Article Inspection Requirement
- AS9103A (2012): Aerospace series - Quality Management System – Variation Management of Key Characteristics
- AS9110C (2016): Quality Management Systems - Requirements for Aviation Maintenance Organizations
- AS9120B (2016): Quality Management Systems - Requirements for Aviation, Space and Defense Distributors
- XP PR EN 9130 (2001): Aerospace Series - Quality System - Document Archiving
- AS9131C (2017): Aerospace Series - Quality Management Systems – Nonconformance Data Definition and Documentation
- AS9132B (2015): Aerospace series - Quality Management Systems - Data Matrix Quality Requirements for Parts Marking
- AS9133A (2016): Aerospace Series - Quality Management Systems - Qualification Procedure for Aerospace Standard Products
- ARP9134A (2014): Aerospace Series - Quality Systems – Supply Chain Risk Management Guideline

Note: XP PR is for experimental standard unlike all the others which are approved standards.

ISO 31000 (2018): Risk Management - Guidelines proposes a generic approach to making risk management effective.

ISO 31010 (2019): Risk Management - Risk Assessment Techniques provides recommendations (guidelines) for selecting and applying systematic risk assessment techniques.

ISO 10007 (2017): Quality Management Systems - Guidelines for configuration management is recommended as a guide for configuration management (see AS9100D sub-clause 8.1.2).

All of these standards and many more can be ordered in electronic or paper format on the ISO site. More than 28,000 standards (in English and other languages) are available on the Public.Resource.Org site.

As recalled in clause 1 of the AS9100D standard in case of conflict, statutory and regulatory requirements always prevail over those of the standard. For your company, check the EU Regulation EC 216/2008 on Civil Aviation Rules and the European Aviation Safety Agency and EC 1702/2003, which lay down rules implemented for the Airworthiness and

environmental certification of aircraft and associated products, parts and equipment, as well as certification of design and production organizations.

The AS9100D standard fully incorporates the 10 clauses of ISO 9001: 2015 (normal characters) and adds specific requirements for the aviation, space and defense industry (in bold italic type). Some of these requirements:

- special requirements
- critical items
- key characteristics
- project management
- risk management
- control of transfer of work
- recall of equipment
- product safety
- counterfeit parts
- customer notification of changes
- approval of external providers
- evaluation of test reports
- first article inspection
- configuration management

2.2 Definitions

The beginning of wisdom is calling things by their proper names. Chinese proverb

Certain definitions and acronyms:

AQMS: *aerospace quality management system*
Competence: *personal skills, knowledge and experiences*
Conformity: *fulfillment of a specified requirement*
Corrective action: *action to eliminate the causes of nonconformity or any other undesirable event and to prevent their recurrence*
Counterfeit part: *unauthorized copy, imitation, replacement part or modified part, deliberately presented as an authentic part*
Critical item: *item which can require specific actions to control its effect*
Customer: *anyone who receives a product*
Customer satisfaction: *top priority objective of every quality management system*
Documented information: *any support allowing the treatment of information*
Effectiveness: *capacity to realize planned activities with minimum efforts*
Efficiency: *financial relationship between achieved results and used resources*
External provider (supplier): *an entity that provides a product*
FMEA: *failure mode and effects analysis*
Indicator: *value of a parameter, associated with an objective, allowing the objective measure of its effectiveness*
Interested party: *person, group or company affected by the impacts of an organization*
Key characteristics: *attribute which can require specific actions to manage its variation*
Management system: *set of processes allowing objectives to be achieved*
Nonconformity: *non-fulfillment of a specified requirement*
Organization (company): *a structure that satisfies a need*
Process: *activities which transform inputs into outputs*
Product (or service): *every result of a process or activity*

Product safety: *the state in which a product is capable of achieving its purpose without causing an unacceptable risk of harm to persons or property*
Quality: *aptitude to fulfill requirements*
Quality management: *activities allowing the control of a company with regard to quality*
Quality management system: *set of activities allowing the achievement of the quality objectives*
Quality manual: *document specifying the general measures taken by an organization to obtain conforming products and services*
Quality objective: *quality related, measurable goal that must be achieved*
Quality plan: *document specifying the methods, means, responsibilities and stages of activities related to quality, applied specifically to a product, project or process*
Quality policy: *statement by top management allowing the establishment of quality objectives*
Requirement: *explicit or implicit need or expectation*
Risk: *probability of occurrence of a potential hazard*
Special requirement: *requirement at the limit of its technical capability*
System: *set of interacting processes*
Top management: *group or persons in charge of the company's control at the highest level*

In the terminology of quality management systems, do not confuse:

- accident and incident
  - an accident is an unexpected serious event
  - an incident is an event which can lead to an accident
- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
  - anomaly is a deviation from what is expected
  - defect is the non-fulfillment of a requirement related to an intended use
  - dysfunction is a degraded function which can lead to a failure
  - failure is when a function has become unfit
  - nonconformity is the non-fulfillment of a requirement in production
  - reject is a nonconforming product which will be destroyed
  - waste is when there are added costs but no value
- audit program and plan
  - an audit program is the annual planning of the audits
  - an audit plan is the description of the audit activities
- audit, inspection, auditee and auditor
  - an audit is the process of obtaining audit evidence
  - an inspection is conformity verification of a process or product
  - an auditee is the one who is audited
  - an auditor is the one who conducts the audit
- control and optimize
  - control is meeting the objectives
  - optimize is searching for the best possible results
- customer, external provider and subcontractor
  - a customer receives a product
  - an external provider provides a product on which specific work is done
  - a subcontractor provides service or product on which specific work is done
- effectiveness and efficiency
  - effectiveness is the level of achievement of planned results
  - efficiency is the ratio between results and resources
- follow-up and review
  - follow-up is the verification of the obtained results of an action
  - review is the analysis of the effectiveness in achieving objectives

- inform and communicate
  - to inform is to give someone meaningful data
  - to communicate is to pass on a message, to listen to the reaction and discuss
- objective and indicator
  - an objective is a sought after commitment
  - an indicator is the information on the difference between the pre-set objective and the achieved result
- organization and enterprise, society, company
  - organization is the term used by the ISO 9001 standard as the entity between the supplier and the customer
  - enterprise, society, company are examples of organizations
- process, procedure, product, activity and task
  - a process is how we satisfy the customer using people to achieve the objectives
  - a procedure is the description of how we should conform to the rules
  - a product is the result of a process
  - an activity is a set of tasks
  - a task is a sequence of simple operations

Remark 1: the use of ISO 9000 and AS9100D definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.

Remark 2: the customer can also be the user, the beneficiary, the trigger, the ordering party or the consumer.

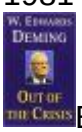
Remark 3: documented information is any information which we must maintain (procedure) or retain (record).

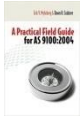
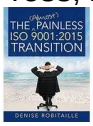
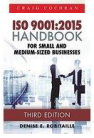
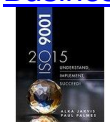
For other definitions, comments, explanations and interpretations that you don't find in this module and in annex 06, you can consult:

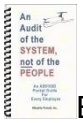
- ISO 9000: 2015 - Quality management systems. Fundamentals and vocabulary, (ISO, 2015)
- Quality management system – Indicators and synoptical tables (FD X50 - 171, ISO, 2000)

2.3 Books

Books for further reading on quality and aviation:

-  Philip Crosby, Quality is free; the Art of Making Quality Certain, McGraw-Hill, 1979
-  Kaoru Ishikawa, What is Total Quality Control, The Japanese Way, Prentice-Hall, 1981
-  Edwards Deming, Out of the Crisis, MIT Press, 1982

-  Eliyahu Goldratt, Jeff Cox, The Goal, A Process of Ongoing Improvement, North River Press, 1984
-  Masaaki Imai, KAIZEN, The Key to Japan's Competitive Success, McGraw-Hill, 1986
-  James Harrington, Poor-Quality Cost, Dekker, 1987
-  Larry Webber, Michael Wallace, Quality Control for Dummies, Wiley, 2007
-  Erik Myhrberg, Dawn Crabtree, A Practical Field Guide for AS9100, ASQ Quality Press, 2010
-  Denise Robitaille, The (Almost) Painless ISO 9001:2015 Transition, Paton Professional, 2015
-  Jan Gillet, Implementing Iso 9001:2015: Thrill your customers and transform your cost base with the new gold standard for business management, Infinite Ideas, 2015
-  Charles Cianfrani, John West, ISO 9001:2015 Explained, ASQ Quality Press, 2015
-  Craig Cochran, ISO 9001:2015 in Plain English, Paton Professional, 2015
-  Denise Robitaille, ISO 9001:2015 Handbook for Small and Medium-Sized Businesses, Quality Press, 2016
-  Alka Jarvis, Paul Palmes, ISO 9001: 2015: Understand, Implement, Succeed!, Prentice hall, 2016
-  Ray Tricker, ISO 9001:2015 for Small Businesses, Routledge, 2016
-  K Thomas, Implement AS 9100 Rev D for Business Excellence: Quality Management System Requirements for Aviation, Space and Defence Organisations, includes ISO 9001:2015, Thomas Orchard Publishers, 2017

- 

Edward Link, An Audit of the System, not of the People - An AS9100D Pocket Guide for Every Employee, Quality Pursuit, 2017

When I think of all the books still left for me to read, I am certain of further happiness.
Jules Renard

3 Process approach

3.1 Process

The word process comes from the Latin root procedere = go, development, progress (Pro = forward, cedere = go). Each process transforms inputs into outputs, creating added value and potential nuisances.

A process has three basic elements: inputs, activities and outputs. 

A process can be very complex (launch a rocket) or relatively simple (audit a product). A process is:

- repeatable
- foreseeable
- measurable
- definable
- dependent on its context
- responsible for its external providers

A process is, among other things, determined by its:

- title and type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documented information
- inputs
- outputs (intentional and not intentional)
- restraints
- people
- material resources
- objectives and indicators
- person in charge (owner) and actors (participants)
- means of inspection (monitoring, measurement)
- mapping
- interaction with other processes
- risks and potential deviations
- opportunities for continual improvement

A process review is conducted periodically by the process owner (cf. annex 02).

Review: *a survey of a file, product, process so as to verify if pre-set objectives are achieved*

The components of a process are shown in figure 3-1: 

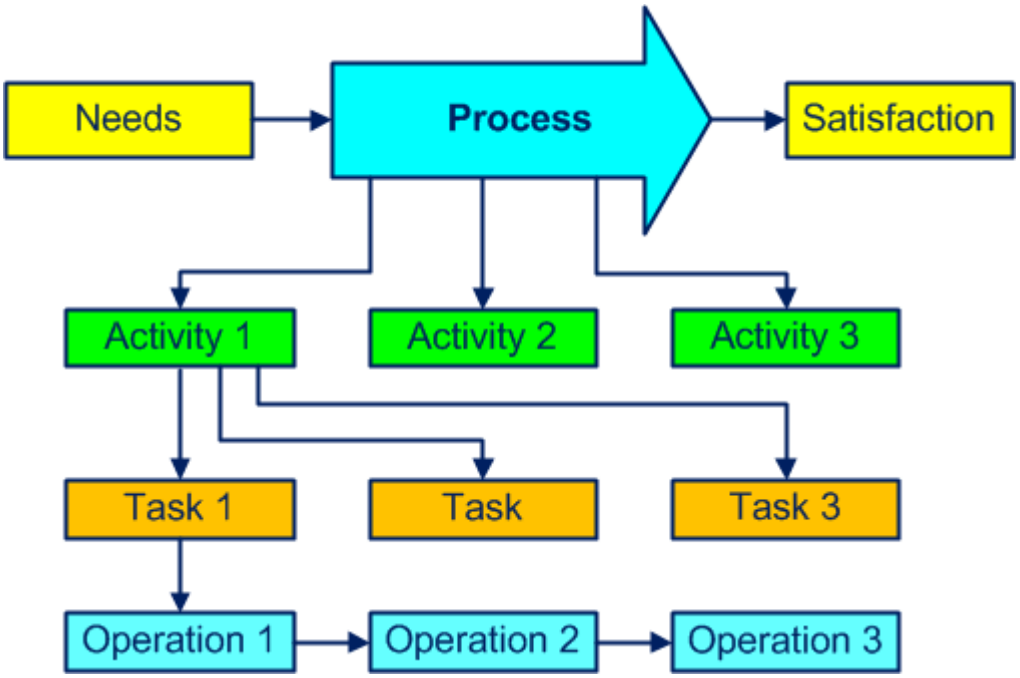


Figure 3-1. Components of a process

Figure 3-2 shows an example that helps to answer some questions:

- which materials, which documents, which tooling? (inputs)
- which title, which activities, requirements, constraints? (process)
- which products, which documents? (outputs)
- how, which inspections? (methods)
- what is the level of performance? (indicators)
- who, with what competence? (people)
- with what, which machines, which equipment? (material resources)

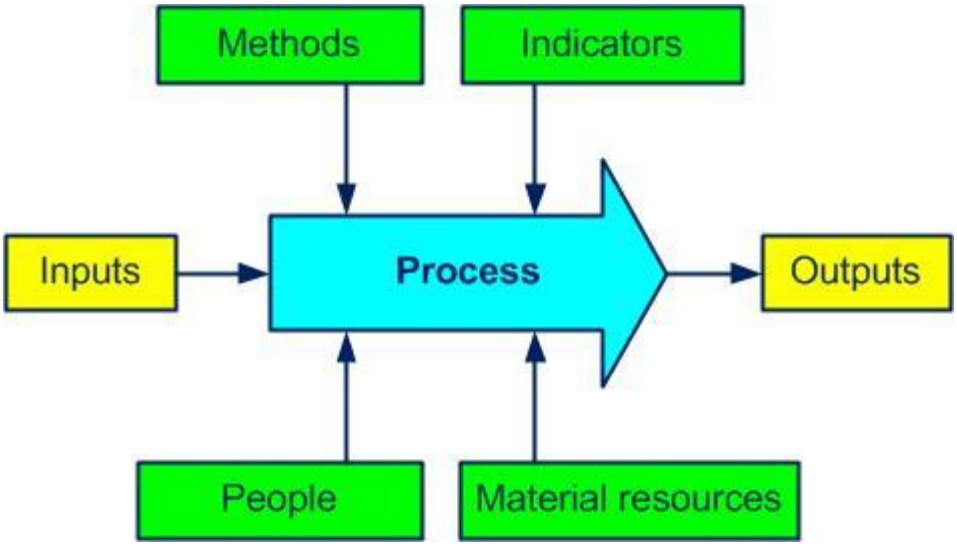


Figure 3-2. Some elements of a process

Often the output of a process is the input of the next process.

You can find some examples of process sheets in the document pack D 02 and a list of processes in annex 03.

Any organization (company) can be considered as a macro process, with its purpose, its inputs (customer needs and expectations) and its outputs (products/services to meet customer requirements).

Our preference is to identify a process using a verb (buy, produce, sell) instead of a noun (purchases, production, sales) to differentiate the process from the company's department or documented information to maintain and recall the purpose of the process.

The processes are (as we shall see in the following paragraphs) of management, realization and support types. Do not attach too much importance to process categorizing (sometimes it's very relative) but ensure that all the company's activities at least fall into one process.

3.1.1 Management processes

Management processes are also known as piloting, decision, key or major processes. They take part in the overall organization, elaboration of the policy, deployment of the objectives and all needed checks. They are the glue holding together all of the realization and support processes.

The following processes can be part of this family:

- develop strategy
- establish process ownership
- establish policy
- deploy objectives
- plan the AQMS
- address risks
- acquire and manage resources
- communicate
- conduct an audit
- carry out management review
- negotiate contract
- meet requirements
- analyze data
- improve

3.1.2 Realization processes

The realization (operational) processes are related to the product, increase the added value and contribute directly to customer satisfaction.

They are mainly:

- maintain equipment
- recall equipment
- manage critical items
- transfer of work
- manage operational risk
- guarantee product safety
- deter counterfeit parts
- design and develop
- carry out FMEA
- notify customers on changes

- purchase components
- control outsourced processes
- approve external providers
- evaluate test reports
- produce
- inspect production
- receive, store and deliver
- inspect first article
- apply traceability
- sell products
- control nonconformities
- implement corrective actions

A specific aspect of the aerospace industry is the use of special processes such as:

- chemical treatment
- coating
- defrosting
- heat treatment
- welding
- surface improvement and many others

A broad consensus was reached on standards and accreditation of processes and special products by Nadcap (National Aerospace and Defense Contractors Accreditation Program).

3.1.3 Support processes

The support processes provide the resources necessary for the proper functioning of all other processes. They are not directly related to a contribution of the product's added value, but are still essential.

The support processes are often:

- control documentation
- provide information
- manage staff
- provide training
- keep accountability
- acquire and maintain infrastructure
- manage inspection means
- manage configuration

3.2 Process mapping

Par excellence process “mapping” is a multidisciplinary work. This is not a formal requirement either of ISO AS9100D or ISO 9001 but is always welcome.

The 3 types of processes and some interactions are shown in figure 3-3 (to simplify the figure, some processes are not shown).

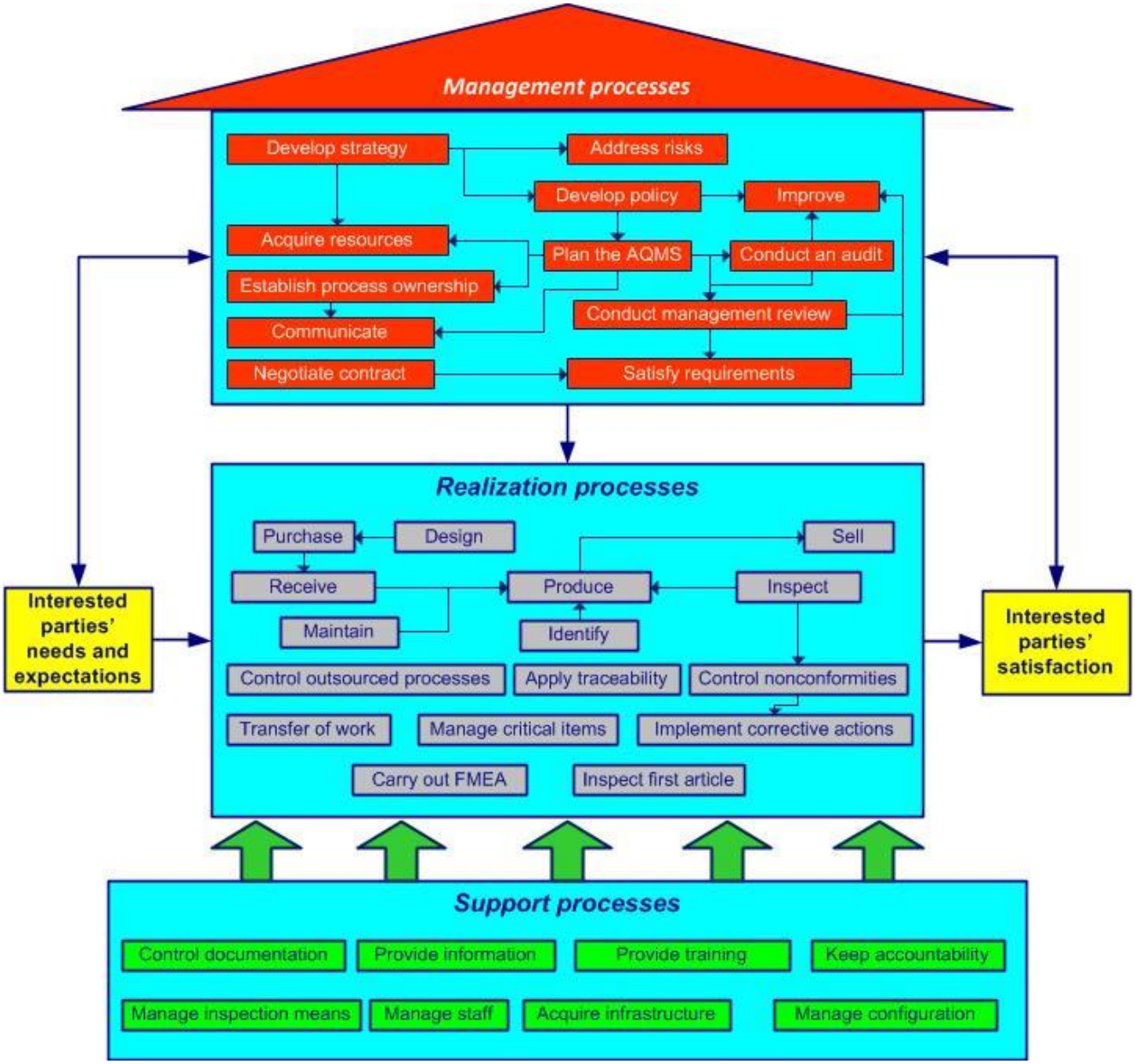


Figure 3-3. The process house

Examples of interested parties: investors, customers, employees, external providers, society

Mapping, among other things, allows you to:

- obtain a global vision of the company
- identify the beneficiaries (customers), flows and interactions
- define rules (simple) for communication between processes

To obtain a clearer picture, you can simplify by using a total of about fifteen core processes. A core process can contain several sub-processes: for example, the process "develop the AQMS" can involve: 

- develop strategy
- establish policy
- plan the AQMS
- address risks

- communicate
- acquire resources
- establish process ownership
- improve

Two other process examples ("design", figure 3-4 and "produce", figure 3-5) are:

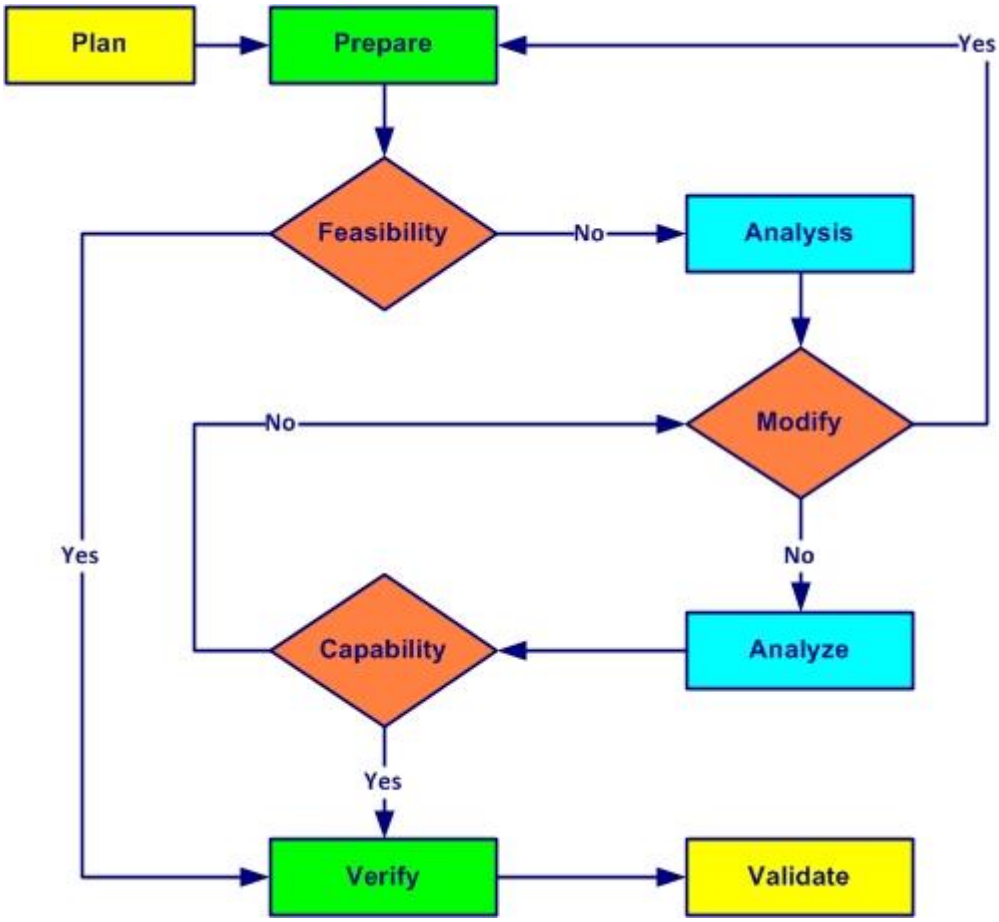


Figure 3-4. Design process

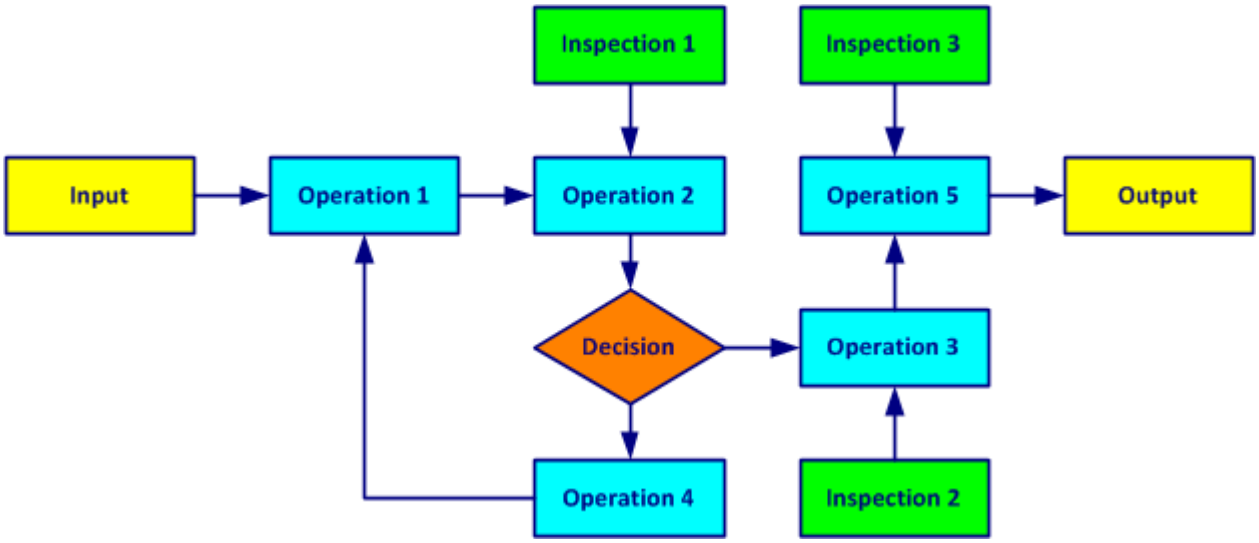


Figure 3-5. Produce process

3.3 Process approach

Simple solutions for now, perfection for later

The process approach contributes enormously to the efficient management of the company (cf. annex 04).

Process approach: *management by the processes to better satisfy customers, improve the effectiveness of all processes and increase global efficiency*

When process approach is integrated during the development, implementation and continual improvement of an aerospace quality management system, it allows one to achieve objectives that are related to customer satisfaction, as is shown in figure 3-6.

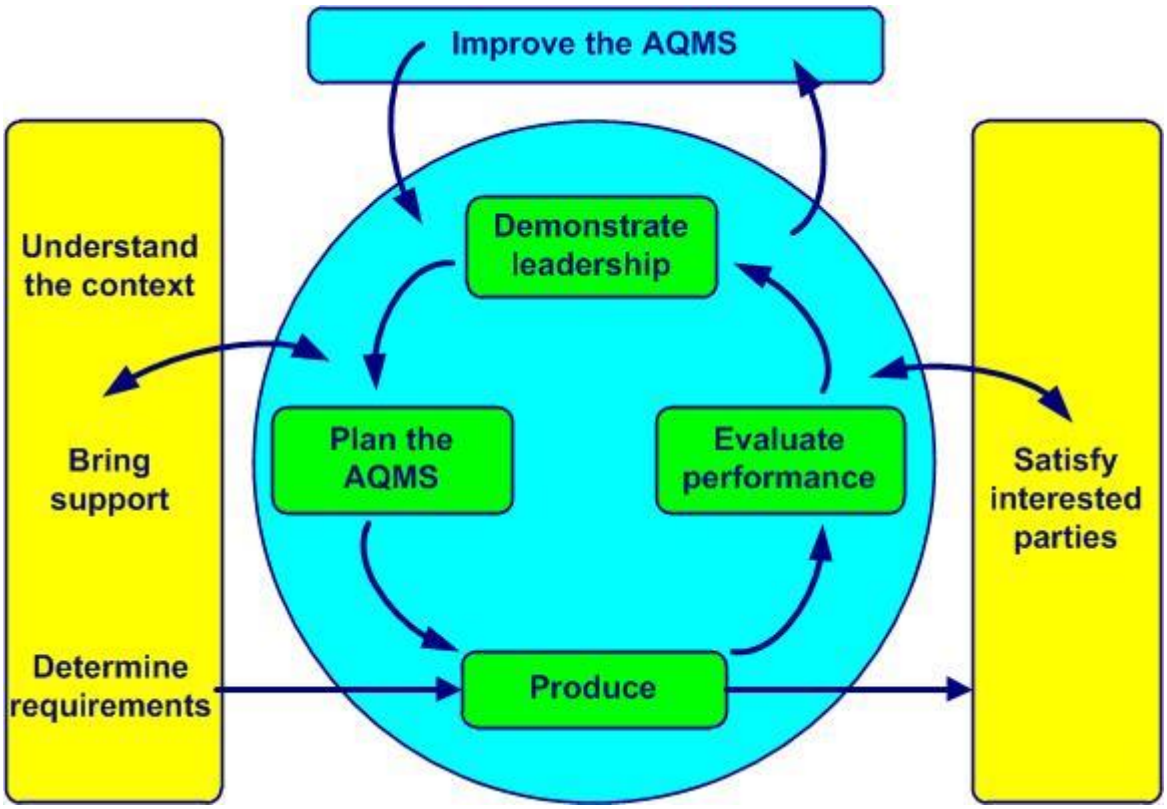


Figure 3-6. Model of an AQMS based on process approach and continual improvement

The process approach:

- emphasizes the importance of:
  - understanding and complying with customer requirements
  - prevention so as to react to unwanted elements such as:
    - customer returns
    - waste
  - measuring process performance, effectiveness and efficiency
  - permanently improving objectives based on pertinent measurements
  - process added value
- relies on:
  - methodical identification
  - interactions
  - the sequence and
  - process management which consists of:
    - determining objectives and their indicators

        - piloting related activities
        - analyzing obtained results
        - permanently undertaking improvements
- allows one to:
    - better view inputs and outputs and their relationship
    - clarify roles and responsibilities
    - judiciously assign necessary resources
    - break down barriers between departments
    - decrease costs, delays and wastes
- and ensures in the long run:
    - control
    - monitoring and
    - continual improvement of processes

The process approach **is not**:

- crisis management ("You will not solve the problems by addressing the effects")
- blaming people (“Poor quality is the result of poor management." Masaaki Imai)
- priority to investments (“Use your brain, not your money." Taiichi Ohno)

4 Context of the organization

4.1 The organization and its context *(requirements 1 to 2)*

The two most important things do not appear in the company's balance sheet: its reputation and its people. Henry Ford

To successfully implement an aerospace quality management system, we must understand and evaluate everything that can influence the reason for being and business performance. You should think carefully about a few key activities:

- develop a thorough diagnosis of the unique context in which your company exists, taking into account these issues:
  - the external environment, such as:
    - social
    - regulatory
    - economic
    - technology
  - the internal environment, such as:
    - specific aspects of the corporate culture:
      - vision
      - rationale, purpose, mission
      - core values
    - staff
    - products and services
    - infrastructure
- monitor and review regularly any information relating to external and internal issues
- analyze the factors that may influence the achievement of business objectives

The SWOT and PESTEL analyzes can be useful for relevant analysis of business context (cf. annex 07).

A list of external and internal issues is carried out by a multidisciplinary team. Each issue is identified by its level of influence and control. Priority is given to issues with great influence and poor control.

Good practices

- *diagnosis of the context includes the main external and internal issues*
- *the core values as part of the corporate culture are taken into account in the context of the company*
- *the results of the context analysis are widely diffused*
- *the SWOT analysis includes many relevant examples*
- *the SWOT analysis is a powerful tool for identifying the main threats and opportunities*

Bad practices

- *the issues of the context of the company, such as the competitive environment, are not taken into account*
- *in some cases, the corporate culture is not taken into account*
- *risk analysis does not take into account strategic issues*

- *no clear link between the SWOT analysis and the actions undertaken*

4.2 Needs and expectations of interested parties *(requirements 3 to 5)*

There is only one valid definition of a business purpose: to create a customer. Peter Drucker

To understand the needs and expectations of interested parties, we must begin by determining those who may be affected by the aerospace quality management system, such as:

- employees
- customers
- external providers
- owners
- shareholders
- bankers
- distributors
- competitors
- citizens
- neighbors
- social and political organizations

A list of interested parties is created by a multidisciplinary team. Every interested party is determined by its level of influence and control. Priority is given to interested parties with great influence and poor control.

True story

The customer is king but we still can fight against rudeness. This example is from the restaurant La petite Syrah in Nice and its coffee prices:

"A coffee".....7 €
"A coffee, please".....4,25 €
"Hello, a coffee, please"....1,40 €

Anticipating the reasonable and relevant needs and expectations of interested parties is:

- meeting the requirements of the product or service offered
- preparing to address risks
- finding improvement opportunities

When a requirement is accepted, it becomes an internal requirement of the AQMS.

Quality means including the customer's point of view from design to final recycling

A review of product and service requirements (including up to delivery) is conducted to:

- ensure that these requirements can be met and are:
  - explicit
  - implicit
  - statutory and regulatory
  - specific to:
    - the company
    - the customer and other interested parties
- determine and address gap situations

This review is performed after receipt of the order and prior to acceptance thereof. A feasibility study may be undertaken.

Good practices

- *the list of interested parties is updated*
- *the needs and expectations of interested parties are established through meetings on site, surveys, roundtables and meetings (monthly or frequent)*
- *the application of statutory and regulatory requirements is a prevention approach and not a constraint*

Bad practices

- *statutory and regulatory requirements are not taken into account*
- *the delivery time is not validated by the customer*
- *the expectations of interested parties are not determined*
- *the list of customers is incomplete*
- *the list of interested parties does not contain their area of activity*

4.3 Scope of the aerospace quality management system *(requirements 6 to 12)*

In many areas, the winner is the one who is best informed. André Muller

The scope (or in other words, the perimeter) of the aerospace quality management system is defined. When a requirement cannot be applied, a justification is included in the documented information that is maintained and is available to any interested party.

The specific context of the company is taken into account to determine the scope of the AQMS, including:

- issues (cf. sub-clause 4.1)
- products and services
- corporate culture
- environment:
  - social
  - financial
  - technology
  - economic
- requirements of interested parties (cf. sub-clause 4.2)
- outsourced processes

Good practices

- *the scope is relevant and available upon request*
- *non applicable requirements are justified in writing*

Bad practices

- *some products are outside the scope of the AQMS without justification*
- *the paint shop is not included in the scope of the AQMS*
- *the requirements of a customer are not accepted and no justification is present*
- *the scope is obsolete (the new subsidiary is not included)*

4.4 Aerospace quality management system and its processes *(requirements 13 to 30)*

If you cannot describe what you are doing as a process, you do not know what you're doing. Edwards Deming

Product requirements are specified by the customer, the company or by regulation.

The requirements of the AS9100D standard include:

- management through quality
- aerospace requirements
- customer and applicable statutory and regulatory requirements and
- the control of business processes

To do this:

- the aerospace quality management system is:
  - established
  - documented (a simple and sufficient documentation system is set up)
  - implemented and
  - continually improved
- interested parties are determined (cf. sub-clause 4.2.a)
- the scope of the AQMS is determined
- the quality policy, objectives, resources and the work environment are determined
- risks are determined and actions to reduce them are established (cf. sub-clause 6.1)
- the core necessary AQMS processes are controlled:
  - corresponding resources are ensured
  - staff is involved
  - the inputs and outputs are determined
  - the necessary information is available
  - owners are appointed (responsibilities and authorities defined)
  - sequences and interactions are determined
  - each process is measured and monitored (established criteria)
  - objectives are set and performance indicators analyzed
  - process performance is evaluated
  - necessary changes are implemented to achieve the expected results
  - actions for continual improvement of processes are established
- the necessary minimum ("as much as needed") of documented information on the processes is maintained and retained ( )

Certain requirements of the standard may not apply to the aerospace quality management system in relation to the size and complexity of the business and the nature of the specific risks and opportunities. A requirement of the AS9100D standard may not be applied when this:

- does not affect in any way:
  - product and service conformity
  - improving customer satisfaction
- does not relieve the company of its responsibilities
- is justified in the quality manual

The quality manual is not a requirement of ISO 9001 version 2015 or AS9100D (this is a possibility, cf. the note at the bottom of sub-clause 4.4.2). This is always an opportunity to present the company, its AQMS and its procedures and processes (cf. annex 07).

Pitfalls to avoid:

- going overboard on quality
- forgetting to take into account the specificities related to the corporate culture and the context in which the company is located
- all documented information being written by the quality manager

In the simplified diagram of figure 4-1, we can see the purpose of an AS9100D aerospace quality management system:

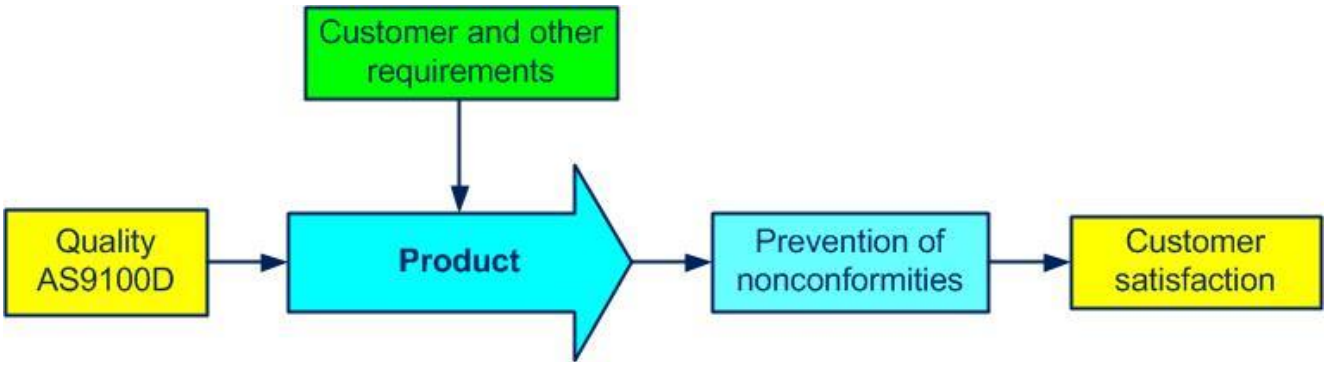


Figure 4-1. Purpose of an AQMS

The requirements of the AS9100D standard in clauses 4 to 10 are shown in figures 4-2:

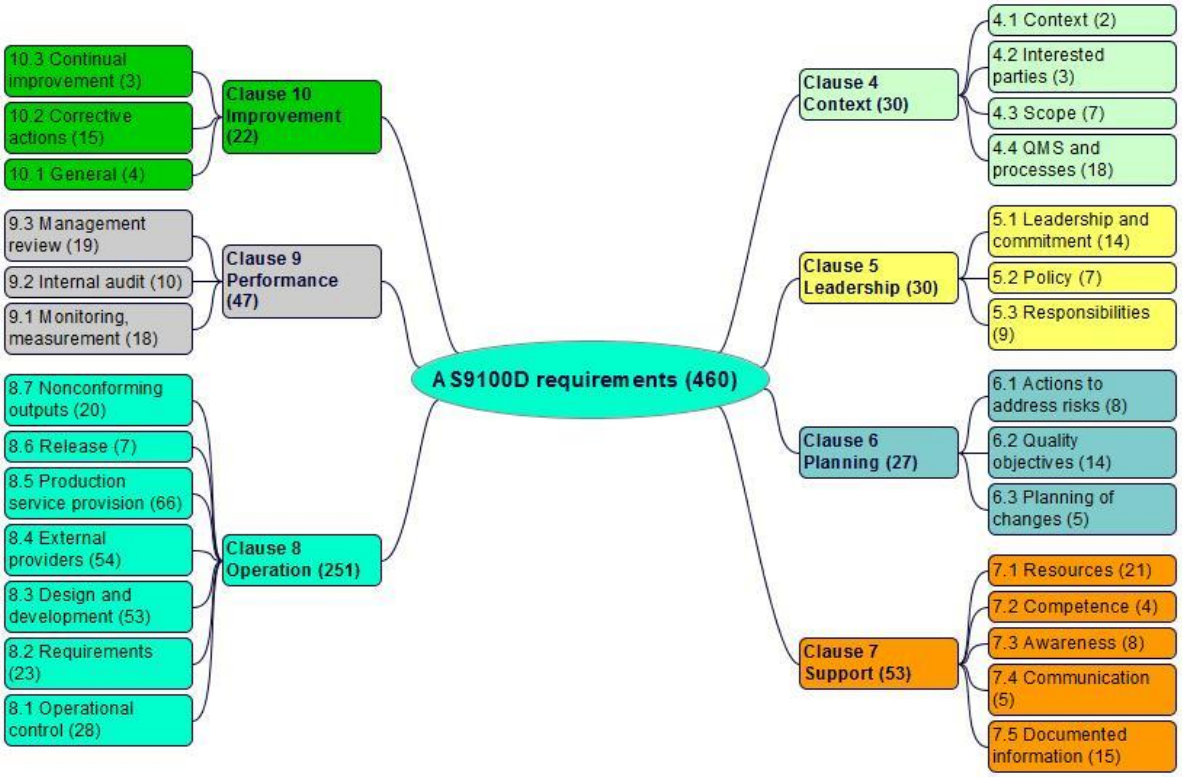


Figure 4-1. The requirements of the AS9100D standard

Good practices

- *the process map has enough arrows to show who the customer (internal or external) is*
- *for a process, it is better to use a lot of arrows (several customers) rather than to forget one*
- *reveal the added value of the process during the process review*
- *the analysis of process performance is an example of continual improvement evidence of the effectiveness of the AQMS*
- *top management regularly monitors the objectives and action plans*
- *the purpose of each process is clearly defined*

Bad practices

- *some process outputs are not set correctly (customers not considered)*
- *process efficiency criteria are not established*
- *process owners are not formalized*
- *outsourced processes are not determined*
- *control of outsourced services is not described*
- *sequences and interactions of certain processes are not determined*
- *criteria and methods for ensuring effective processes are not determined*
- *monitoring the effectiveness of certain processes is not established*
- *AQMS resources do not allow achievement of quality objectives*
- *the AQMS is not updated (new processes not determined)*
- *the threats and weaknesses identified in the SWOT analysis remain without actions*