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BACKGROUND - WHAT IS ISO?

The International Organization for Standards (ISO) is a network of the national standards institutes of 151 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization: its members are not, as is the case in the United Nations system, delegations of national governments. Nevertheless, ISO occupies a special position between the public and private sectors. This is because many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. Some members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.

ISO creates a standardization of practices and processes. ISO is the largest developer of technical standards in the world.

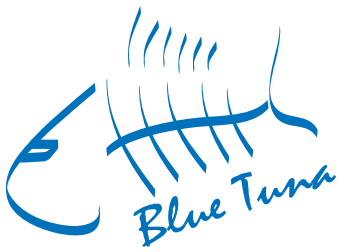
ISO standards contribute to making the development, manufacturing and supply of products and services more efficient, safer and cleaner. They make trade between countries easier and fairer. They provide governments with a technical base for health, safety and environmental legislation. They aid in transferring technology to developing countries. ISO standards also serve to safeguard consumers, and users in general, of products and services - as well as to make their lives simpler.

AS9100

Using ISO 9001:2000 as a baseline, SAE (Society of Automotive Engineers), The Engineering Society for Advancing Mobility Land Sea Air and Space International® included additional requirements, traceable to the Code of Federal Regulations. These regulations are particularly important to the aerospace industry. As a result SAE AS9100 Rev B Quality Systems was established. Many of the "add-ins" are directly traceable to Title 14.

Title 14 - Aeronautics and Space Chapter I - FAA, Department of Transportation Subchapter C - Aircraft

Part 21	Certification procedures for products and parts
§21.3	Reporting of failures, malfunctions and defects
§21.95	Approval of minor changes in type design
§21.97	Approval of major changes in type design
Part 39	Airworthiness Directives
§39.3	Definition of Airworthiness Directives
Part 45	Identification and Registration Marking
§45.11	General
§45.13	Identification of data
§45.14	Identification of critical components
§45.15	Replacement and modification parts
§45.16	Marking of life - limited parts



AS9100

Info

AS9100 IS BUILT FROM THE ISO STANDARD

There are three types of AS9100 Quality Management Systems

AS9100

Designed for manufacturing organizations.

AS9110

Designed for service organizations.

AS9120

Applicable to aerospace parts distributors.

AS9100 defines additional areas within an aerospace quality management system that must be addressed when implementing an ISO 9001:2000-based quality system. Typically, these requirements are included within robust aerospace quality systems. The industry experts who wrote the standard and the representatives who approved it all agree that these additions are essential to ensure product, process and service safety and quality.

Although the standard outlines industry “**whats**” for a quality management system, the “**how tos**” were deliberately left out and remain the system designers’ responsibility. This reflects the AS9100

writing team’s belief that how-to information stifles continuous improvement.

All quality systems must be designed to meet the specific needs of the users. And although AS9100 identifies areas to address within the aerospace industry, system designers are encouraged to first establish a robust quality system that’s both effective and efficient.

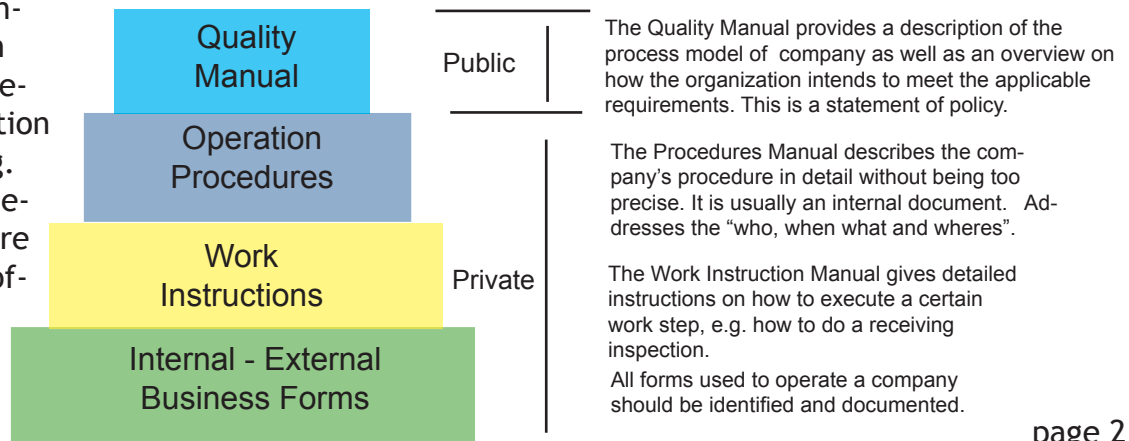
Many Repair Stations already have quality systems of some type in place. Most existing quality systems typically become Operation Procedures. It is important to take advantage of existing procedures already in place. Changes will occur as your company adopts a process based approach to quality management.

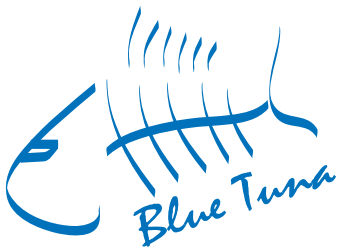
THE RELATIONSHIP BETWEEN AS9100 AND YOUR ORGANIZATION

EXAMPLE: FAA PART 145 REPAIR STATION DOCUMENTATION

Repair Stations that implement AS9100 as their quality system typically already have documentation in place to support the AS9100 Quality Manual policy. This documentation usually consists of the Part 145 Repair Station Manual, Operation Procedures, Work Instructions, and Forms.

The typical repair station manual will have a quality section that provides supporting procedures for inspections, calibration of test equipment and tooling. Repair Station Operation Procedures and Work Instructions are often one and the same and offer specific guidance on how to accomplish tasks. Repair Station Forms typically need to be added for the AS9100.





AS9100 - A PROCESS BASED APPROACH

The “Buzz”

Business Process Orientation became a buzz-word in the nineties of the last century. Significant improvements were achieved by focusing on business processes instead of individual functions.

Today, the principles of process orientation are widely used among others as foundation of state-of-the-art Quality Standards such as AS9100.

AS9100 incorporates a Process Orientation as a means to understanding the entire enterprise as a set of processes destined to satisfy customer requirements. Instead of focusing on the efficiency of individual functions it optimizes the effectiveness and throughput of the whole system. Changing from traditional functional orientation to a process approach represents a major paradigm shift for most enterprises.

Thinking in layers of processes instead of functions helps to keep the enterprise focused on what really counts: Consistently meeting and possibly exceeding customer's requirements and expectations.

Therefore, in a process oriented company, the customer is not only the outside customer but basically every process that follows in the sequence of the entire order processing procedure.

Implementing process orientation means defining a process model, determining goals, procedures and resources for each individual sub-process and setting up a management review system that allows for monitoring process effectiveness and efficiency.

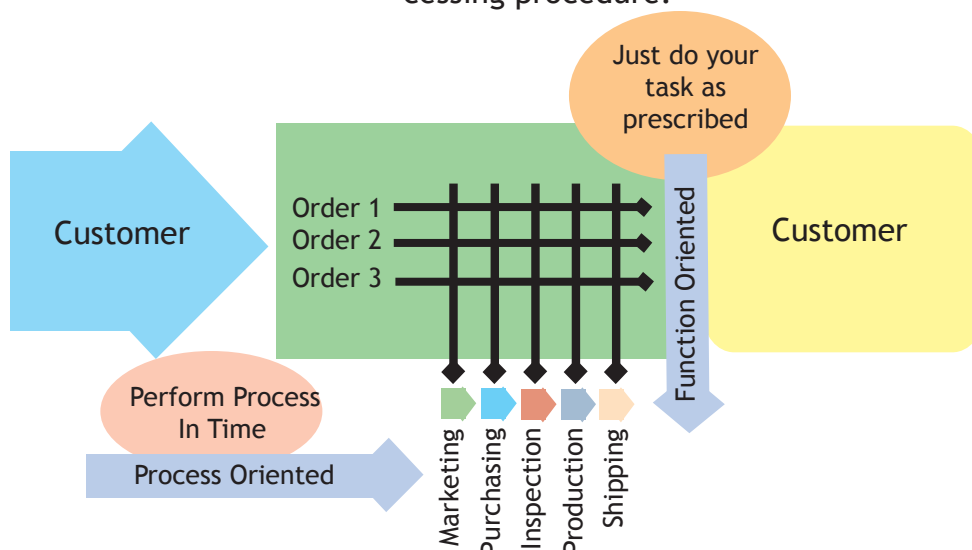
The beginning of the 20th century marked the inclusion of processes in quality practices. *A process is a group of activities that takes an input, adds value to it, and provides an output*, such as when a chef transforms a pile of ingredients into a meal. Dr. Walter Shewhart, a statistician for Bell Laboratories, began to focus on controlling processes in the mid-1920s.

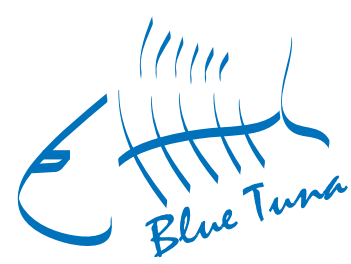
Shewhart recognized that industrial processes yield data. For example, a process in which metal is cut into sheets yields certain measurements: the sheet's length, height, weight, etc. Shewhart determined that this data can be analyzed using statistical techniques to see if a process is stable, or “in control,” or if it is being affected by special causes that should be fixed. In doing so, Shewhart laid the foundation for control charts, a modern-day quality tool.

In sum, Shewhart's concepts are referred to as statistical quality control (SQC). They differ from product orientation in that they make quality relevant not only for the finished product but also for the process that created it.

Source: Quality 101

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AS9100 Info

From the TOP

Implementing a QMS is too big a project for one person. Implementing an QMS will affect all departments and levels of employees. Having a good representation of employees on this team will help ensure the decisions made are appropriate and will help with achieving buy-in across the organization.

IMPLEMENTING AS9100

Moving from a traditional function based system to a process based quality system requires the effort of many people within the organization. For the purpose of understanding how your organization will make the leap (or has made the leap) the process is broken down into five steps.

1 Gap Analysis is the first step.

Setting up a QMS should start with the procedures and QM measures already in place in a company. They need to be reviewed for compliance and completeness regarding the applicable standard. The assessment will identify the adequacy of current procedures and the need for new procedures.

2 QM System Development. Current procedures must be documented. Identify the processes, the sequence and interaction of these processes, needed for the quality management system and their application throughout the organization. Flow chart your processes, describe process inputs and outputs and the interaction of the processes in your organization.

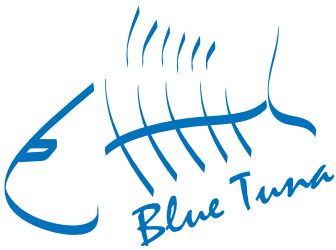
3 Document the QM System this begins with documenting quality policy and objectives.

4 Applicable Requirements should be systematically reviewed while working on procedures and documentation in order to make sure that the system

meets all requirements. Processes, the sequence and interaction of these processes, needed for the quality management system and their application throughout the organization must be validated.

5 Quality Audits should then be performed by Internal Quality Auditors to verify that the actual proceedings are as documented and that the system as a whole complies with the applicable standard.





TRANSPARENT WORK CULTURE

Transparency

Function orientated models focus on segments and parts. Process based business looks at the whole and seeks the good of the whole.

Limits are place on an organization when it has no way to improve and adapt with the changing needs of technology and the customer.

THE MINIMUM FACTOR
A barrel made out of staves will hold water up to the level of the shortest stave.

Your company is only as strong as your weakest department.

A Process Orientated company is also horizontally based.

That is the focus is on the entire system. Improvement is applied against the whole. Horizontally based companies seek to optimize the effectiveness and throughput of the whole system.

Horizontal based business flow spreads improvement across the entire enterprise. Customers are the focus rather than departments and segments of the product.

Transparency in the work place occurs when employees see themselves as a part of the greater whole. Process based business models are geared towards improvement of the whole. The idea of improving the whole builds and fuels the team.

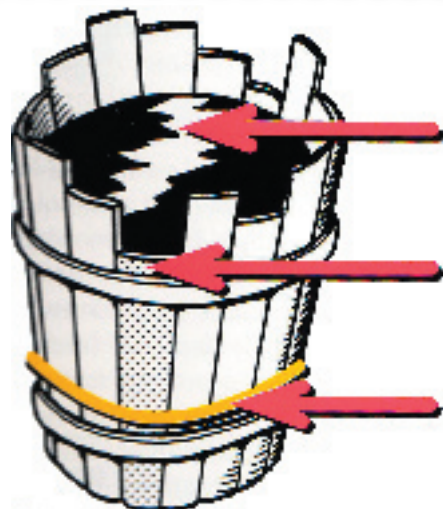
Transparency engenders contribution from employees. Their involvement along with management fuels continuous improvement. In turn the customer experiences satisfaction because of the efficiency and effectiveness of the company.

A Function Orientated company is

vertically based.

The focus falls upon one function instead of the entire system. Improvement is only applied against one segment of the system.

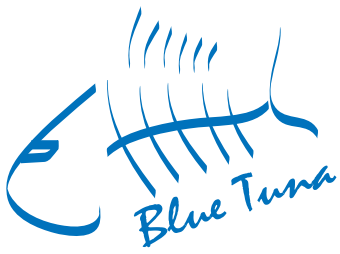
Vertical based business has an isolating impact upon the company. Typically companies like this are top down management models with a focus on individual departments and segments of the product.



Customer Requirements

Company Capabilities

Company System



BUZZ Words

Some of the following may be new phrases or processes you are encountering as you grapple with learning the AS9100 QMS.

Management Review

Top management reviews the Quality Management System at designated intervals to determine its' continued suitability, adequacy and effectiveness.

Configuration Management

Configuration management generally concentrates on technical and organizational activities that establish and maintain control of a product and its configuration information throughout the life cycle of the product.

Product Realization

A product starts out as an idea. The idea is realized or actualized by following a set of product realization processes. So product realization refers to all the processes that are used to bring products into being.

For a detailed list see <http://www.praxiom.com/iso-definition.htm>

WHAT'S NEW?

So, now your organization has a ISO based QMS! What is so different? You may think it is simply a matter of more paperwork, or another manual to read.

What has really happened goes far beyond paperwork. Processes have been added, the organization's focus has changed and there is a feeling of continuous improvement. The organization has become more intensely focused on customer satisfaction. New processes have been created to increase value added activity.

Using a FAA Certified Repair Station as an example you would notice the following changes. Processes and procedures once hand written, or locked away in the owner's mind are now documented in a procedures manual of some type. Effort is made to identify, track and validate key requirements. More people have input and impact into the organization's structure and method of operation.

While the FAA does not endorse or officially approve the new quality manual

they still maintain surveillance over the processes. However, regulatory compliance is maintained at all times. The Quality Management System is driven by Customer Satisfaction and certificated by an accreditation organization that is global. This is the heart of the QMS, the standardization of practices and products.

Another noticable change is how review changes things. Throughout the Quality Manual there are references to "continuous improvement." The process of continuous improvement is built into the standard in order to encourage organizations to review and change to increase effectiveness and efficiency. This in turn improves customer satisfaction.

Your organization's new Quality Manual is the statement of their quality policy and objectives. The procedures used by your organization in the past may have been retuned to make them more effective. These procedures or processes define how you will carry out the organization's quality policy.