



# International Organization for Standardization

**“The effectiveness of using ISO 9001 is simply a matter of how well it is implemented”**





# Introduction to ISO 9001

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# ISO 9001:2015 TOPICS FOR DISCUSSION

- History of ISO 9001:
  - Why Become Certified
  - Benefits of ISO 9001
  - ISO 9001 Requirements:
    - ISO 9001 Structure:
  - ISO 9001 Implementation Plan:
  - ISO 9001 Certification Process
  - Companies ISO Certified
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# HISTORY OF ISO 9001

- **ISO 9000**

- Introduced in 1987
- Used heavily in the Automotive Industry
- Updated in 1994-many issues

- **ISO 9001:2000**

- Created in 2000-combined ISO 9002 and ISO 9003
- Design and Development requirements
- In U.K. ISO demands from gov organizations, engineer contractors

- **ISO 9001:2008**

- Minor changes from 2000 edition

- **ISO 9001:2015**

- New High Level Structure
- Current standard implemented today

# WHY BECOME ISO 9001 CERTIFIED

- Reasons companies become ISO 9001:2015 certified:
  - Certification is recognized worldwide
  - Expand upon current and new markets/industries
  - Gain a competitive advantage over those not certified
  - Many companies today require ISO 9001 certification for quoting opportunities
  - Allows your company to become an APPROVED VENDOR for customers, thus increasing the potential of receiving more orders
  - Tier 1 Supplier
  - Reduces/eliminates customer audits
  - Increased opportunities for expansion
  - ISO 9001 puts an organized, structured system in place
  - High level of consistency to produce quality products and services
  - ISO 9001 system ensures employee accountability



# WHY BECOME ISO 9001 CERTIFIED (CONT)

- Reasons companies become ISO 9001:2015 certified (cont):
  - Provides checks and balances throughout the company
    - Processes completed by one employee will be reviewed by another, thus reducing errors
  - Continual Improvements are intended to make a company operate more efficiently
  - Nonconformances will be monitored, documented, and *will* be reduced
    - NCR's can lead to high waste costs, loss of time, and potential loss of customers
  - Quality, Quality, Quality

# BENEFITS OF ISO 9001 CERTIFICATION (CONT.)

- Benefits of being ISO 9001:2015 certified (cont):

- Well defined and documented procedures improve the consistency of output.
- Quality is constantly measured
- Procedures ensure corrective action is taken whenever defects occur.
- Defect rates decrease
- Defects are caught earlier and are corrected at a lower cost.
- Defining procedures identifies current practices that are obsolete or inefficient.
- Documented procedures are easier for new employees to follow.
- Organizations retain or increase market share, increasing sales or revenues.



# BENEFITS OF ISO 9001 CERTIFICATION (CONT.)

• A well designed and implemented Quality Management System, based on ISO 9001 has been shown to provide organizations with the following benefits:

- You will have consistent, repeatable processes and a common system.
- You will have fewer problems with failures in service or product quality.
- Your people know what to do and how you want it done.
- You will have more business, because you can sell to new markets or having the endorsement will distinguish you in the marketplace.
- You'll know more quickly if things are going wrong, and where;
- You stop spending money or wasting time on the same old problems.
- Many problems will disappear because you know how to prevent them; if they do come up, you'll know how to fix them faster.
- Better management control and reporting - which means that you know how your business is doing



# BENEFITS OF ISO 9001 CERTIFICATION (CONT.)

• BCS clients reported the following benefits from gaining ISO 9001 certification:

- Greater management control
- Greater clarity about what they do and how
- Improvements in customer satisfaction
- Having a 'much better handle' on what they are doing
- Increased employee satisfaction
- Enhanced employee accountability
- Reduced rework and frustration

# BENEFITS OF ISO 9001 CERTIFICATION

- Benefits of being ISO 9001:2015 certified:

- What is a process?

- Process Maps

- Plan-do-check-act



# BENEFITS OF ISO 9001 CERTIFICATION

- Benefits of being ISO 9001:2015 certified:
- Process: Any activity or set of activities that uses resources to transform inputs into outputs.
  - Must have defined objectives, inputs, outputs, activities and resources.

# BENEFITS OF ISO 9001 CERTIFICATION

- You should be able to ask these when defining a process:
  - Activities- What are the basic jobs carried out in your department?
    - Can you explain to me your operations here?
  - Inputs/Resources: ◦ What information do you need to start your work?
    - Where does it come from?
  - Outputs ◦ Who receives the result of your work?
    - How do you know if you've done your job correctly? (meet objectives)



# BENEFITS OF ISO 9001 CERTIFICATION

Procedure - A procedure outlines how to perform a process, such as "Purchasing":

## Procedure Sample

- Who performs what action
- What sequence they perform the steps in the task
- The criteria (standard) they must meet

Your procedures (along with your ISO 9001 quality manual and required forms) make up your quality management system (QMS). Your procedures will describe how you operate and control your business and meet the ISO 9001 requirements.

Procedures are used for all of the Quality System Processes. You need to have all of the ISO 9001 required Procedures to ensure that the QMS runs correctly and consistently.

# BENEFITS OF ISO 9001 CERTIFICATION

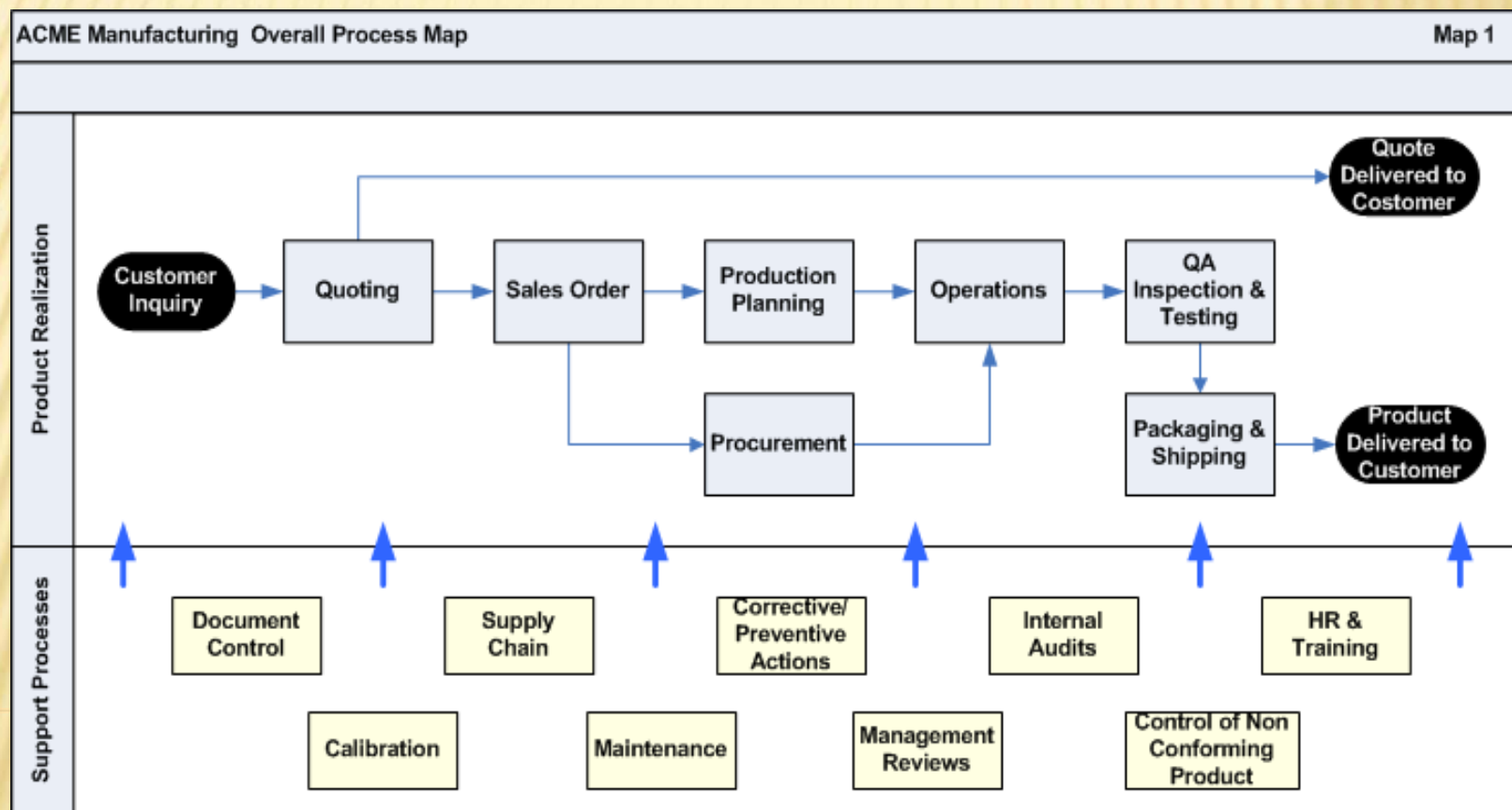
**Work Instructions** - A work instruction describes how to perform a task, which is a more detailed portion of the procedure such as "Completing a PO" or "Ordering supplies".

You may need more detail than that described in the procedures. Many businesses include work instructions to aid in training, to reduce mistakes, a point of reference for jobs, etc.



# BENEFITS OF ISO 9001 CERTIFICATION

- Process Maps



# BENEFITS OF ISO 9001 CERTIFICATION

## • Plan-Do-Check-Act

### PLAN

Establish the objectives and processes necessary to deliver expected results. By making the desired output the focus, it ensures that the completeness and accuracy of the specification is also part of the improvement.

When defining the objectives,

- Define: owner, customer, customer requirements
- Identify/Provide inputs, outputs, resources required, monitoring method & measurement method

### DO

Implement the new processes.



# BENEFITS OF ISO 9001 CERTIFICATION

- Plan-Do-Check-Act

## CHECK

Measure the new processes and compare the results against the expected results to determine any differences.

## ACT

Analyze the differences to determine their cause. Each will be part of either one or more of the P-D-C-A steps. Take Corrective Action, Preventive Action OR Improve The Process

Determine where to apply changes that will include improvement. When these four steps does not result in the need to improve, refine the scope to which PDCA is applied until there is a plan that involves improvement.

# AUDITING PROCESS FLOW

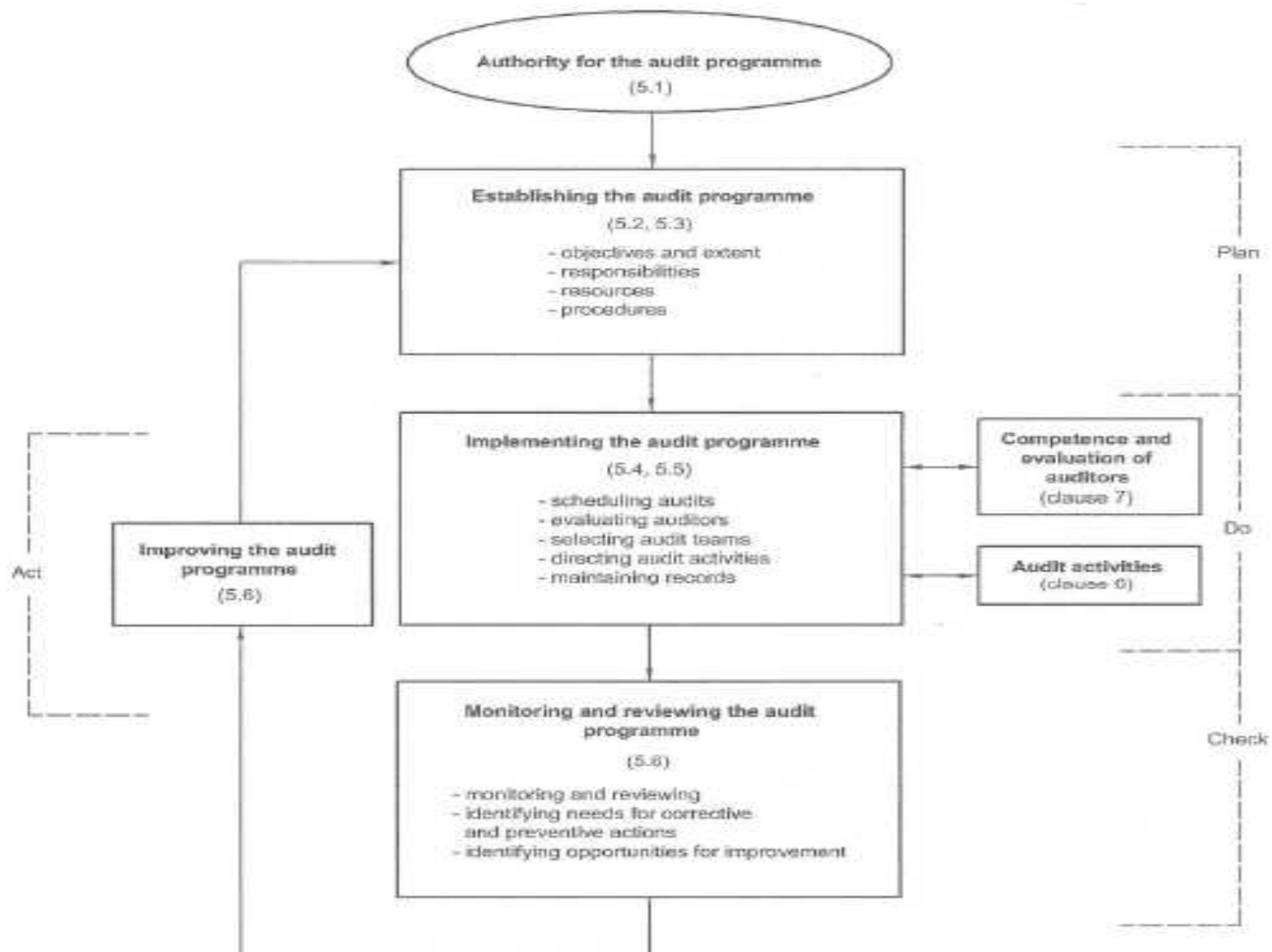
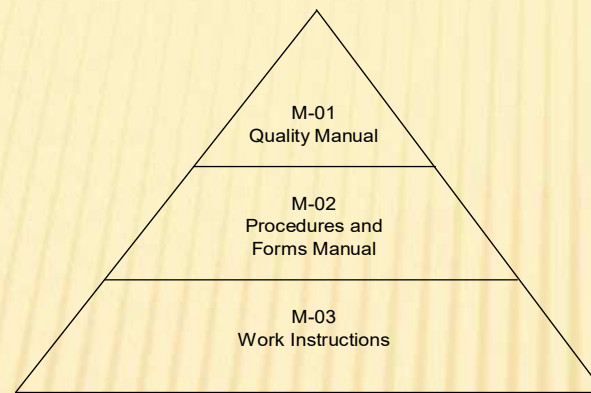


Figure 1 — Illustration of the process flow for the management of an audit programme



# ISO 9001 STRUCTURE

The Quality Management System (QMS) documentation is produced in a three-tier structure as shown.



# ISO 9001 IMPLEMENTATION PLAN

- Barile Consulting Services, LLC (BCS) provides ISO 9001:2015 consulting services for companies within various industries, size and scope. BCS will create:
  - A full ISO 9001:2015 manual for your company
  - The ISO 9001:2015 manual consists of the following:
    - Quality Manual, Procedures, Forms, Work Instructions.



# STEPS FOR IMPLEMENTATION

- Barile Consulting ISO 9001 Implementation Steps Include:
  - Hire a consultant
  - Onsite meetings include BCS and 1-3 ISO 9001 management leaders
  - BCS goes through various questions during each session
  - BCS interviews various departments throughout the process
  - BCS creates all ISO forms after each session
  - BCS creates all ISO procedures for your company
  - Your ISO management leaders will review all ISO forms and procedures created by BCS prior to any audit

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# STEPS FOR IMPLEMENTATION (CONT)

- Barile Consulting ISO 9001 Implementation Steps Include:
  - BCS will perform a full onsite Internal Audit prior to the Certification Audit
  - Once the internal audit is passed the certification audit will be scheduled with an ISO Registrar of desire

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# ISO CERTIFICATION PROCESS

- Here are steps involved with the ISO 9001 Certification Process:
  - Consulting and implementation are complete
  - An Internal Audit has been performed
  - A Management Review has been conducted
  - Contract with an ISO 9001 Registrar
    - Pre-assessment Audit (optional)
    - Stage 1 Audit (document review)
    - Stage 2 Registration Audit
    - Certification Distribution
    - Yearly Surveillance Audits
    - Re-Registration audits every 3 years

# COMPANIES ISO CERTIFIED THROUGH BCS

Name	Location	Size	Business Type
Adv	Columbus, OH	15	Plastics Mfg
Aer	Painesville, OH	10	CNC Machining
Cas	Cleveland, OH	35	Die Cast Mfg
Gas	Cleveland, OH	5	Electrical Products
Ide	Dayton, OH	60	Office Products Mfg
Mid	29 locations	400	Valve Distributor/Mfg
Med	Detroit, MI	15	Medical Products Mfg
PM	Cincinnati, OH Reno, NV Atlanta, GA	58	Babbitt Bearings
Red	Pittsburgh, PA	65	Valve Mfg
SC	Jacksonville, FL	15	Gov Product Mfg