FE 422 FOOD PRODUCTION MANAGEMENT

4. ISO 9000 Quality Management System Standards

Dr. Ali Coşkun DALGIÇ

Role, origins and application of ISO 9000

What is ISO 9000?

ISO 9000:2000 is a series of three International Standards for Quality Management Systems. They specify requirements and recommendations for the design and assessment of management systems. ISO 9000 is not a product standard. None of the standards in the family contain requirements with which a product or service can comply. There are no product acceptance criteria in ISO 9000 so you can't inspect a product against the standard.

Role, origins and application of ISO 9000

What is the purpose of ISO 9000?

The purpose of these standards is to assist organizations of all types to implement and operate effective quality management systems. These standards provide a vehicle for consolidating and communicating concepts in the field of quality management that have been approved by an international committee of representatives from national standards bodies. It is not their purpose to fuel the certification, consulting, training and publishing industries. The primary users of the standards are intended to be organizations acting as either customers or suppliers.

Role, origins and application of ISO 9000

What is the ISO 9000 family of standards?

The three standards in the family are

- ISO 9000 Quality management systems – Fundamentals and vocabulary
- ISO 9001 Quality management systems – Requirements
- ISO 9004 Quality management systems – Guidelines for performance improvements

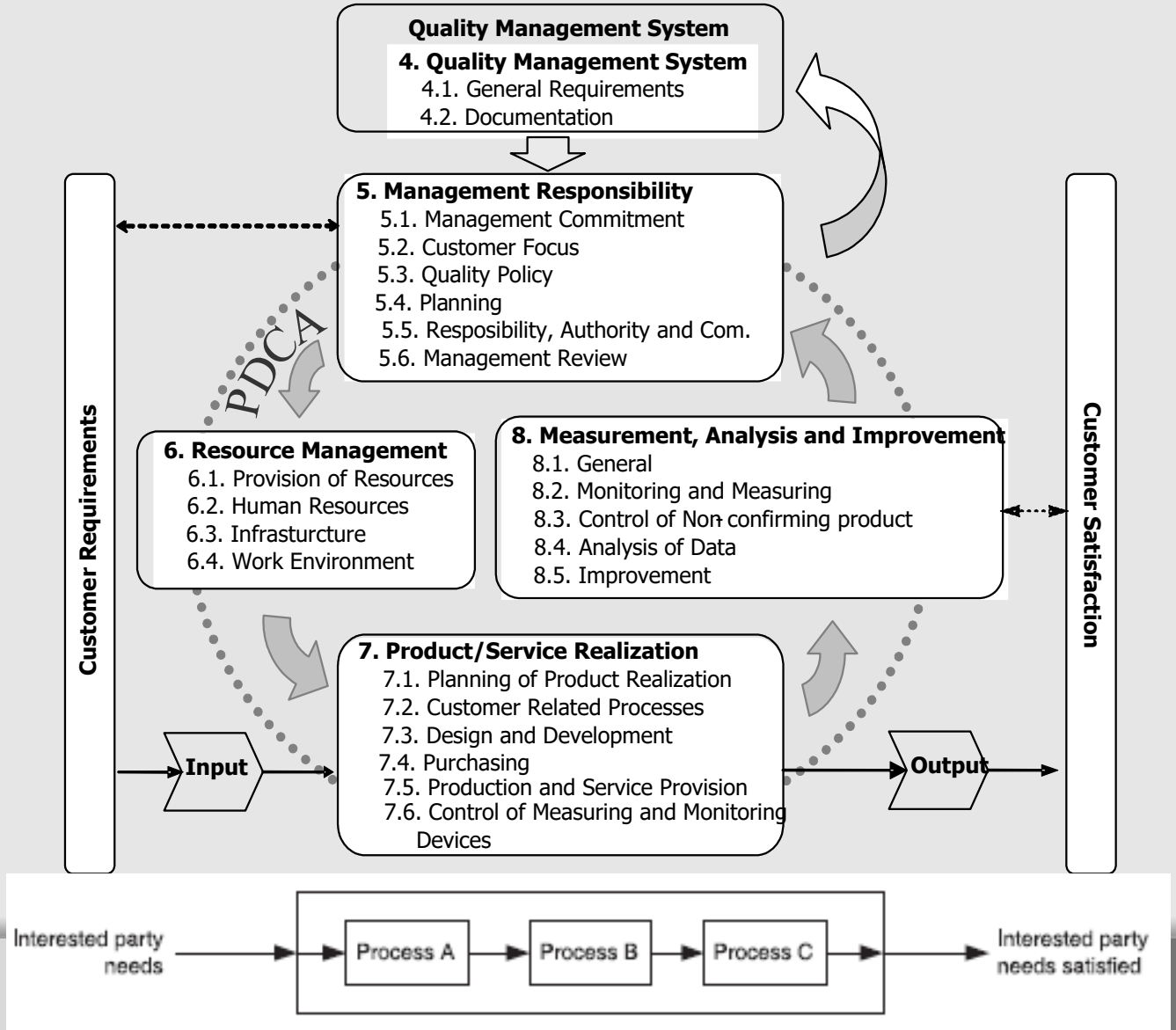
Role, origins and application of ISO 9000

What is the purpose of these standards?

Each standard fulfils a different purpose.

- The purpose of ISO 9000 is to provide an appreciation of the fundamental principles of quality management systems and an explanation of the terminology used in the family of standards.
- The purpose of ISO 9001 is to provide requirements which if met will enable organizations to demonstrate they have the capability to consistently provide product that meets customer and applicable regulatory requirements. ISO 9001 states that *the standard can be used to assess the organization's ability to meet customer, regulatory and the organization's own requirements*.
- The purpose of ISO 9004 is to provide guidance for improving the efficiency, effectiveness and overall performance of an organization.

Model of a process based quality management system



KEYS

Audits Audits of management system design, processes and conformity with ISO 9001 – no longer limited to procedure audits

Communication Processes for internal communication rather than systems of documentation

Continual improvement The effectiveness of the management system to be continually improved – not merely reviewed

Contract Review Replaced by a wide-ranging review of all product requirements including customer, organizational and regulatory requirements – no longer limited to contracts and tenders. The standard has moved away from the original intention of it being used in a contractual situation to one in which there might be no contract until after a product or service has been developed.

Customer satisfaction Customer perceptions of the organization's performance to be monitored as one of the measures of management system performance

Design If the organization designs its own products and services, design and development processes must be included in the management system (see *Exclusions* below)

KEYS

Documentation Determined by the organization as necessary for effective operation of its processes – not simply as required by the standard

Linkages Organization purpose, policy, objectives, processes and results to be linked to demonstrate effective process management

Management review Top management to review the system for its effectiveness in enabling the organization to meet requirements of customers and other interested parties – no longer limited to a review of audit results and customer complaints

Marketing The processes employed to determine customer needs and expectations must form part of the management system – no longer limited to contract review activities

Measurement Required for all processes not only production, servicing and installation processes

Procedures Only six procedures specified as requirements, others as needed for effective operation and control of the processes

Processes All processes that serve the achievement of the organization's objectives to comprise the management system – no longer limited to production, installation and servicing

KEYS

QMS To be designed around the organization's processes not the elements and clauses of the standard

Quality Manual Needs to describe the interaction between processes – is not to be a response to each clause of the standard

Quality objectives Separate from the policy but consistent with it and established at relevant levels and functions – the driver of continual improvement in performance

Quality policy To be appropriate to the purpose of the organization and provides a framework for quality objectives – not a motherhood statement

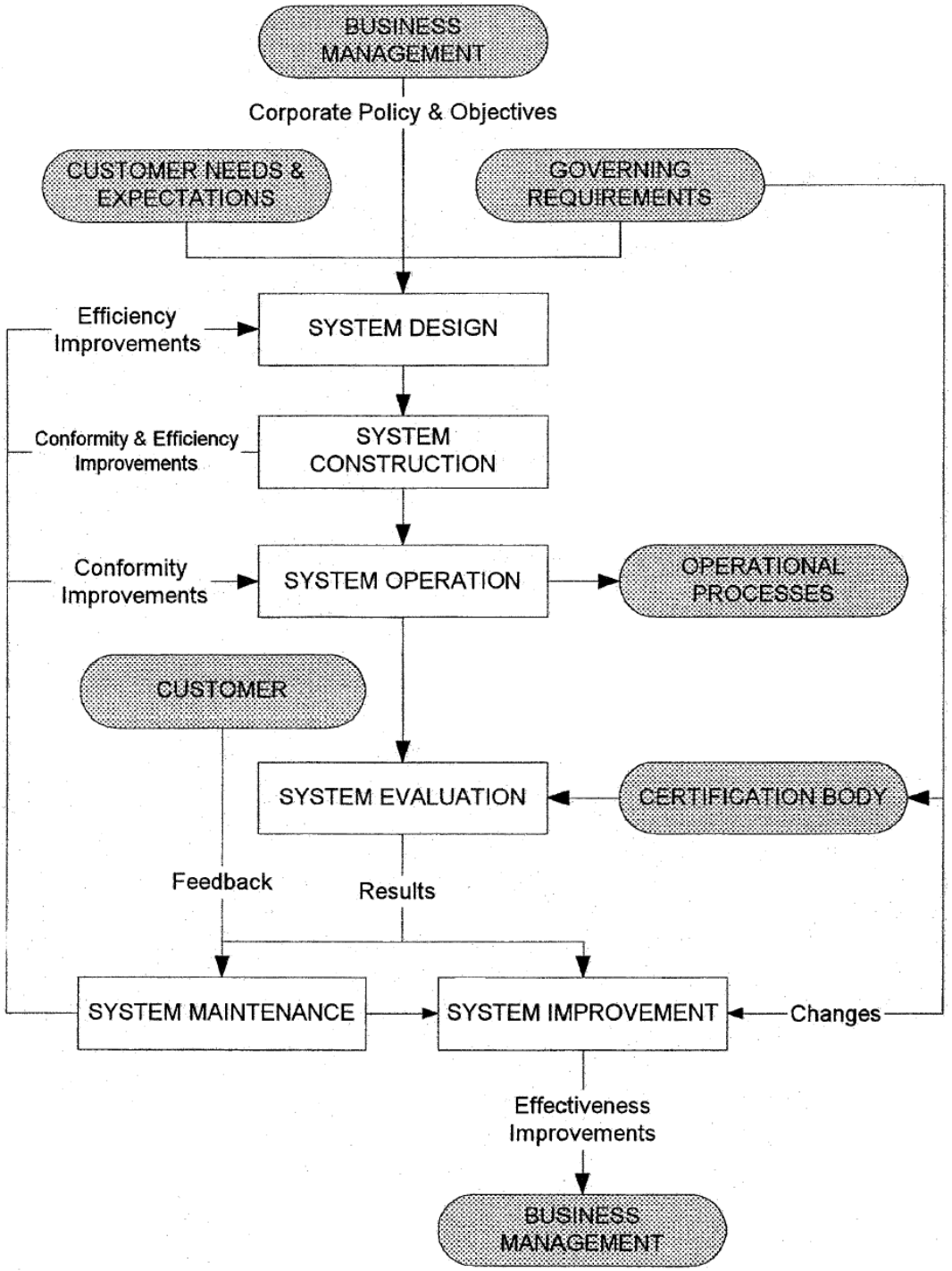
Records As needed to provide evidence of effective operation – all types of records not simply those referred to as quality records

Requirements Commitment to meeting requirements of customer and other interested parties – no longer limited to the organization's own requirements

System effectiveness To be measured, analysed and continually improved and judged by the degree to which customers are satisfied – not judged on conformity with standard

Top management Must be involved in establishing, developing, reviewing and improving the management system

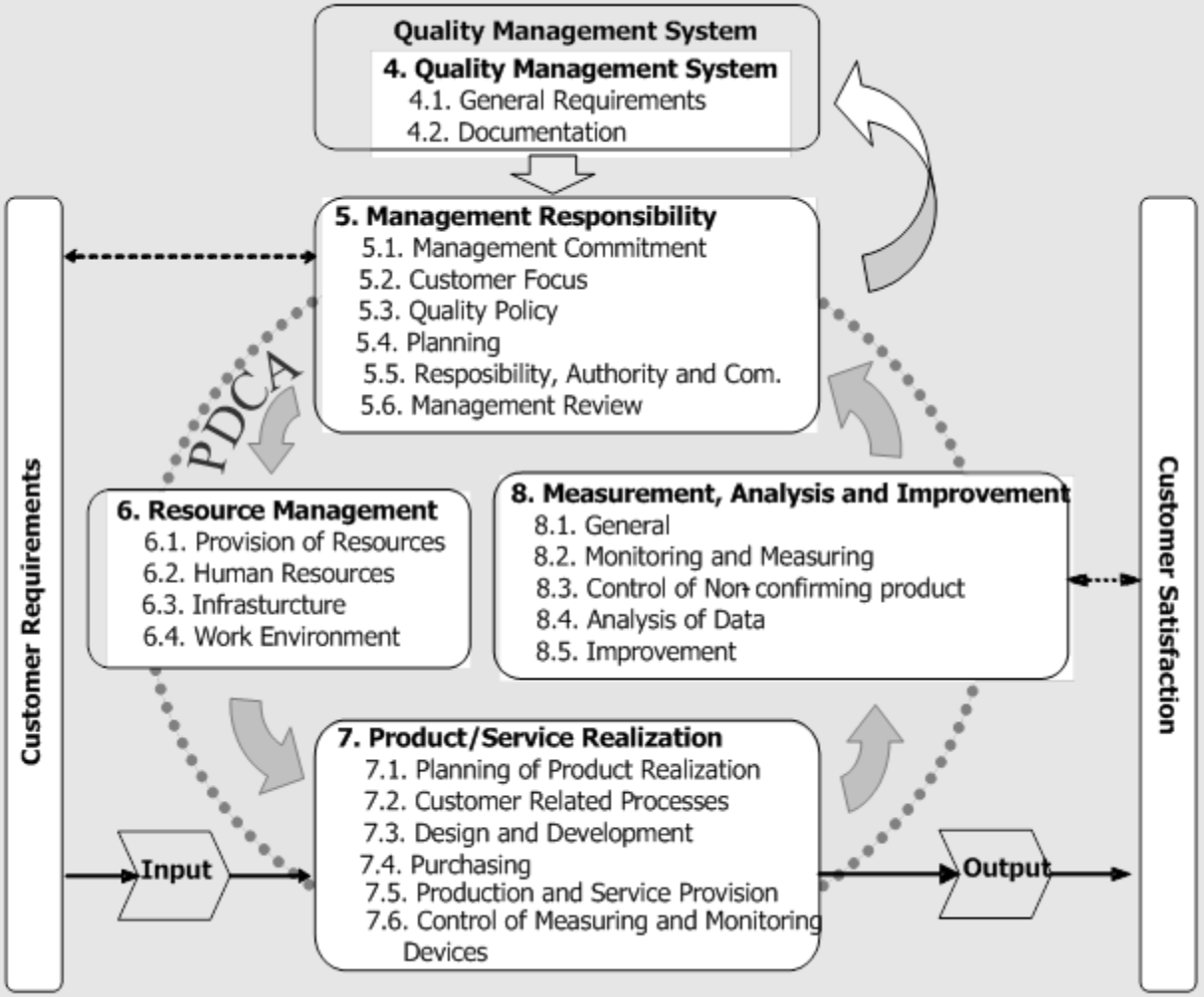
- System management process model



Clause 4.- Documenting a quality management system

- The standard requires the organization to *document a quality management system in accordance with the requirements of ISO 9001*.

- Clause 4.2.1 requires management system documentation to include 5 types of document:
  (a) Quality policy and objectives
  (b) Quality manual
  (c) Documented procedures
  (d) Documents needed to ensure the effective planning, operation and control of processes
  (e) Records



FE 422 FOOD PRODUCTION MANAGEMENT

5. Quality Documentation

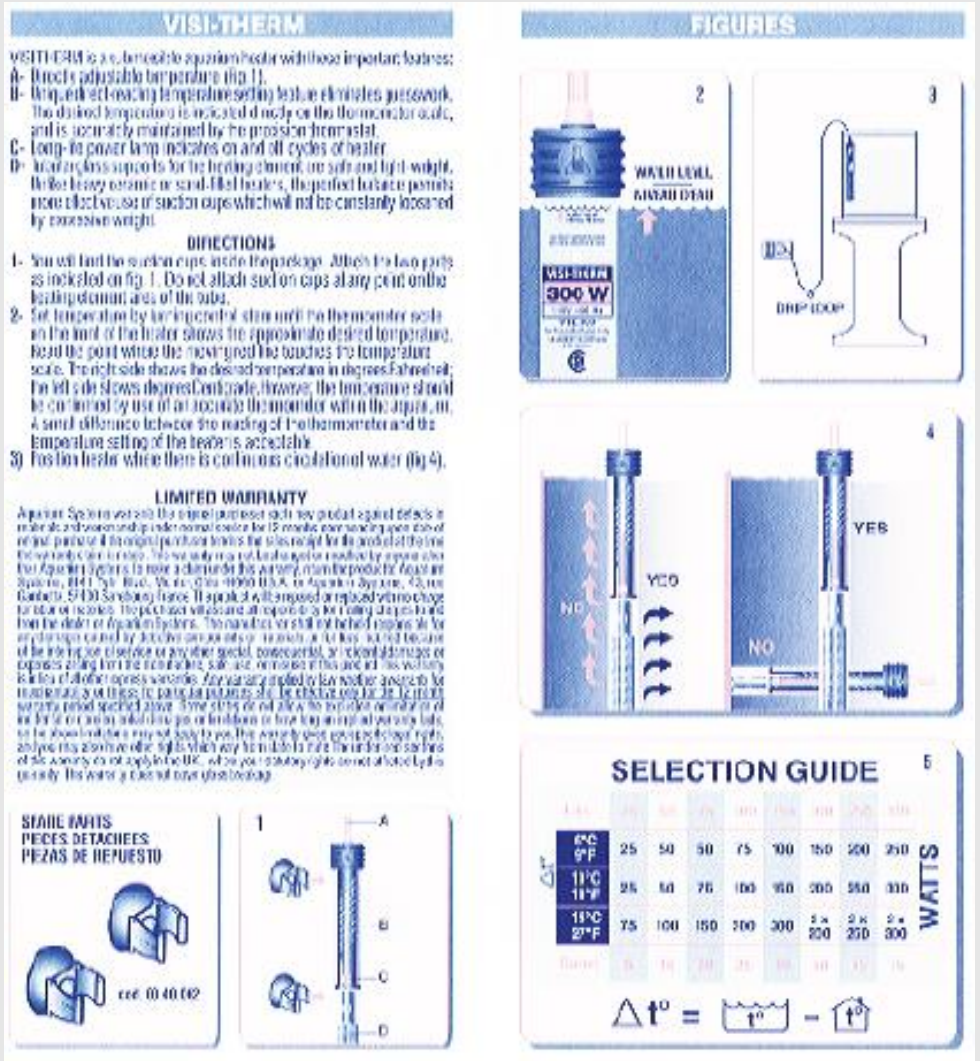
Dr. Ali Coşkun DALGIÇ

What is Documentation?

- Documentation is much talked about. Sectors each have SOPs and maintains a Quality Systems Manual. Each facility has their own specific documentation (which must correlate with Sector and corporate documentation. There is also process documentation in the manufacturing areas.
- Everyone uses documentation outside of work. If you buy something (like a clock), there are instructions in the box. That is documentation.
- Think of documentation as instructions. Documentation explains how to do things.

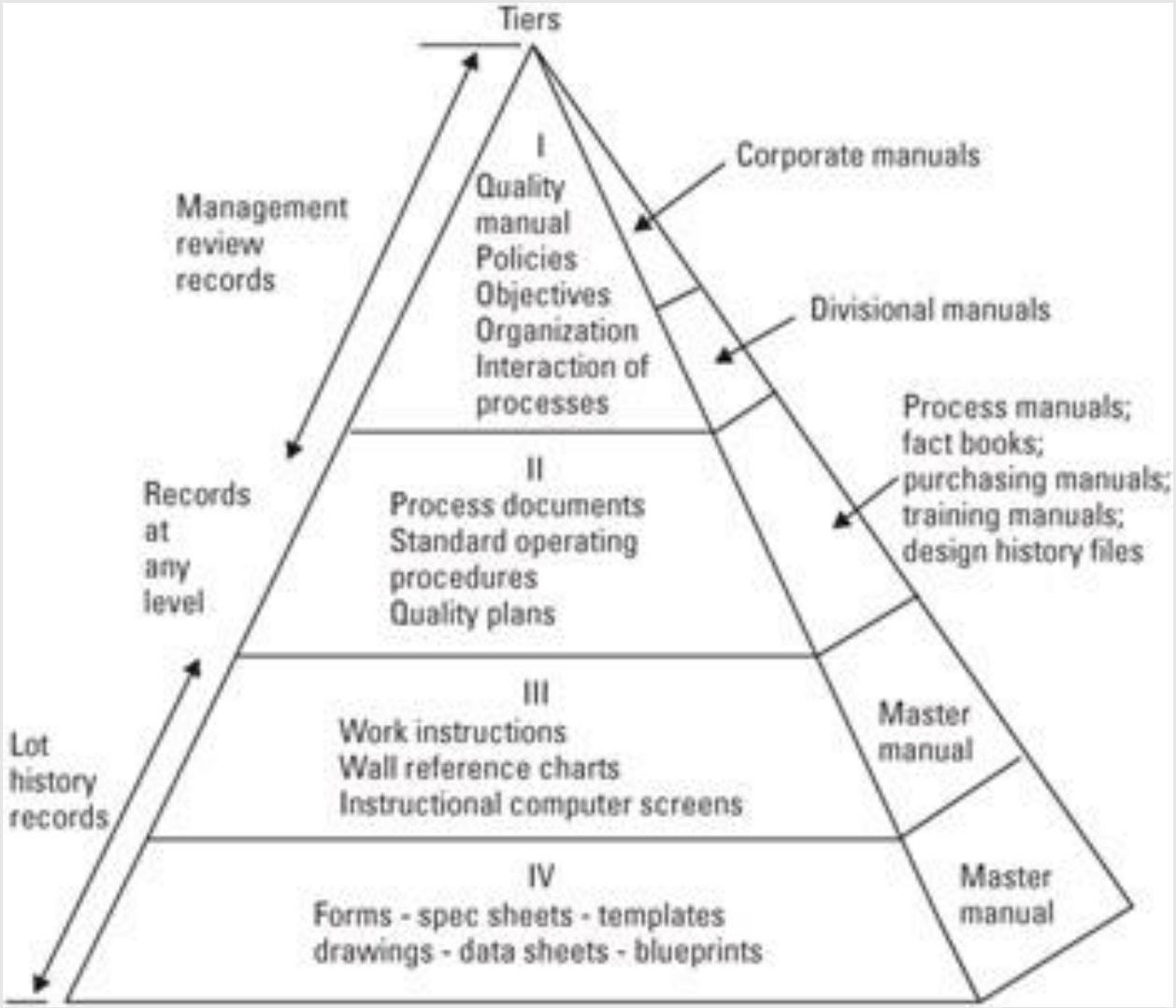
An Everyday Work Instruction

- This is the ‘Work Instruction’ which comes with an aquarium heater. It gives the user some basic information. Note that there are graphics (several in multiple languages) in addition to the basic text. There is also a ‘selection’ guide for the purchaser.



What is Controlled Documentation?

- A controlled document is typically one that is Revision sensitive - BUT - Not always!!
- If a controlled document is changed, a record of the change has to be made. This means we must have a History of All Changes.
- If a document is changed, people who use it must know about the change. This means there has to be a distribution list or other effective way to let everyone who uses it know the document has changed.
- Every employee must know how to check to see if documentation they are using is the most current version.


Tiers
I
Quality manual
Policies
Objectives
Organization
Interaction of processes
Corporate manuals
Divisional manuals
Process manuals; fact books; purchasing manuals; training manuals; design history files
Management review records
Records at any level
II
Process documents
Standard operating procedures
Quality plans
III
Work instructions
Wall reference charts
Instructional computer screens
Master manual
Lot history records
IV
Forms - spec sheets - templates
drawings - data sheets - blueprints
Master manual

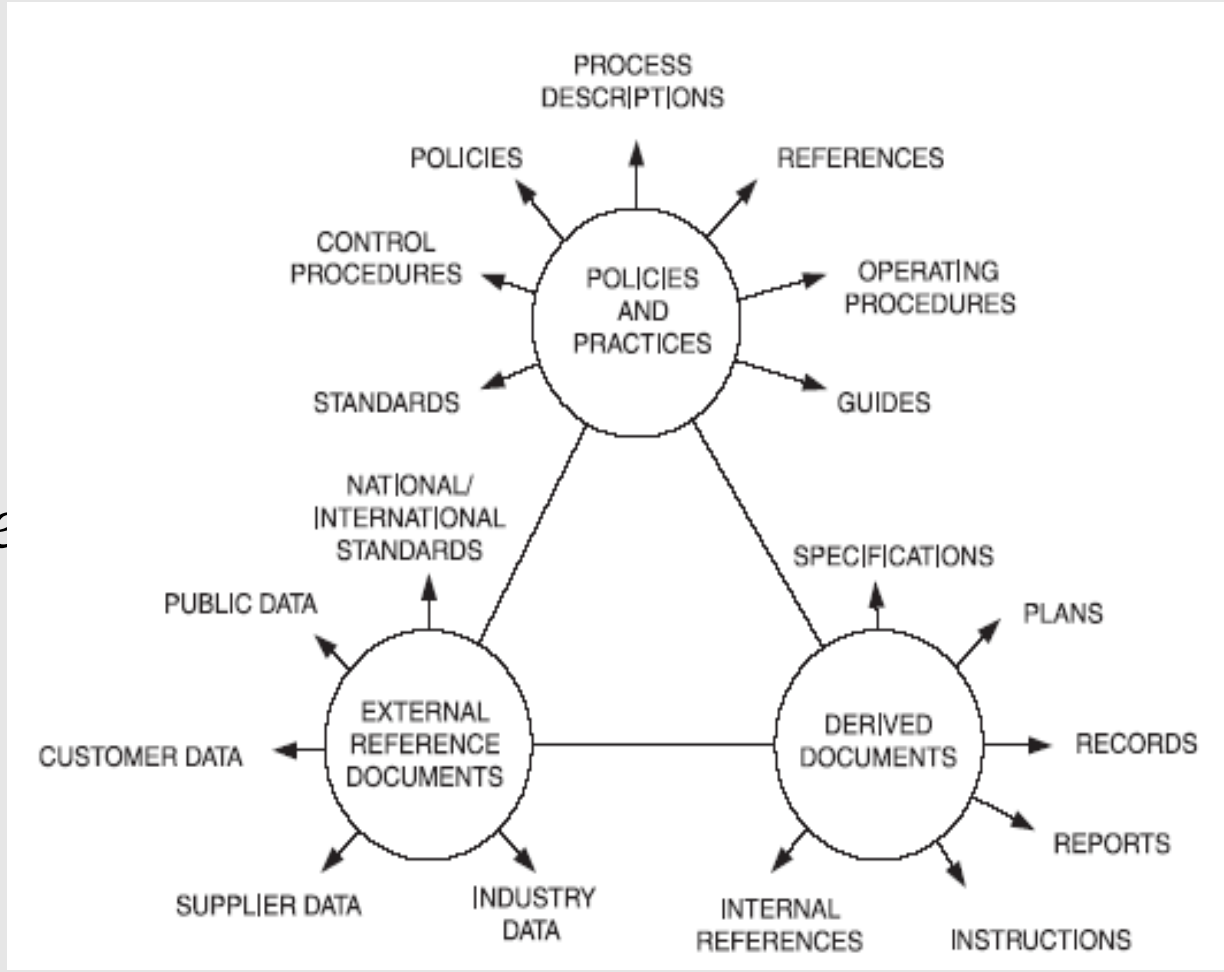
- This is a ‘standard’ documentation pyramid.
- Tier 1 = Policies
- Tier 2 = Think of these as Overviews of major systems (e.g.: Nonconformance system, Purchasing system, etc.
- Tier 3 = The actual systems in detail
- Tier 4 = Objective evidence - Proof that the systems are functioning as well as a source of data for various evaluations (such as inspection & test data).

Documentation

- Organization Charts
- Procedures
- Forms
- Tags
- Prints
- Specifications
- Statistical Data
- Inspection & Test Results

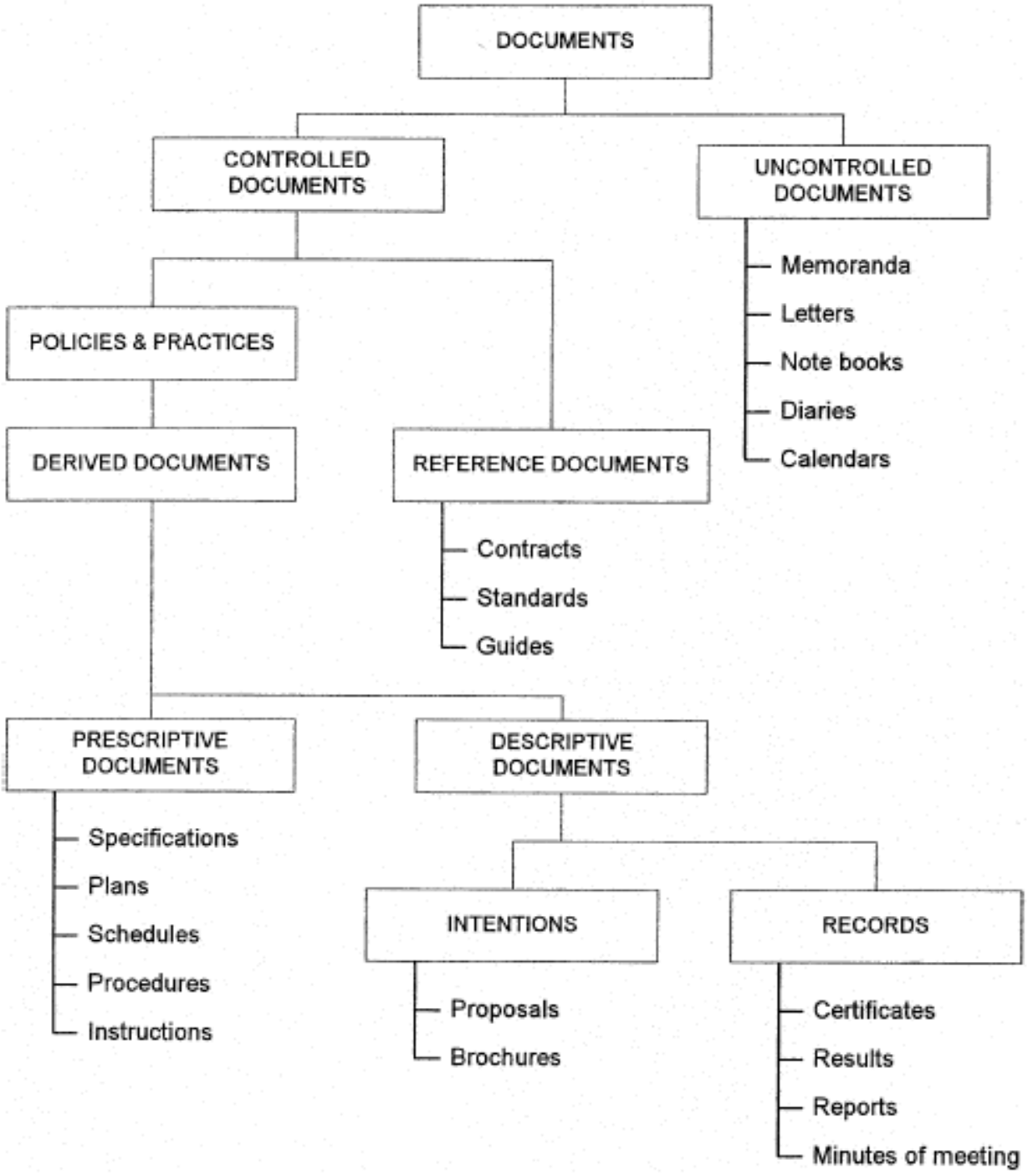
Documents that ensure effective planning, operation and control of processes

- The standard requires management system documentation *to include documents required by the organization to ensure the effective planning, operation and control of its processes*.



Relationships between documents

- Classification of documents

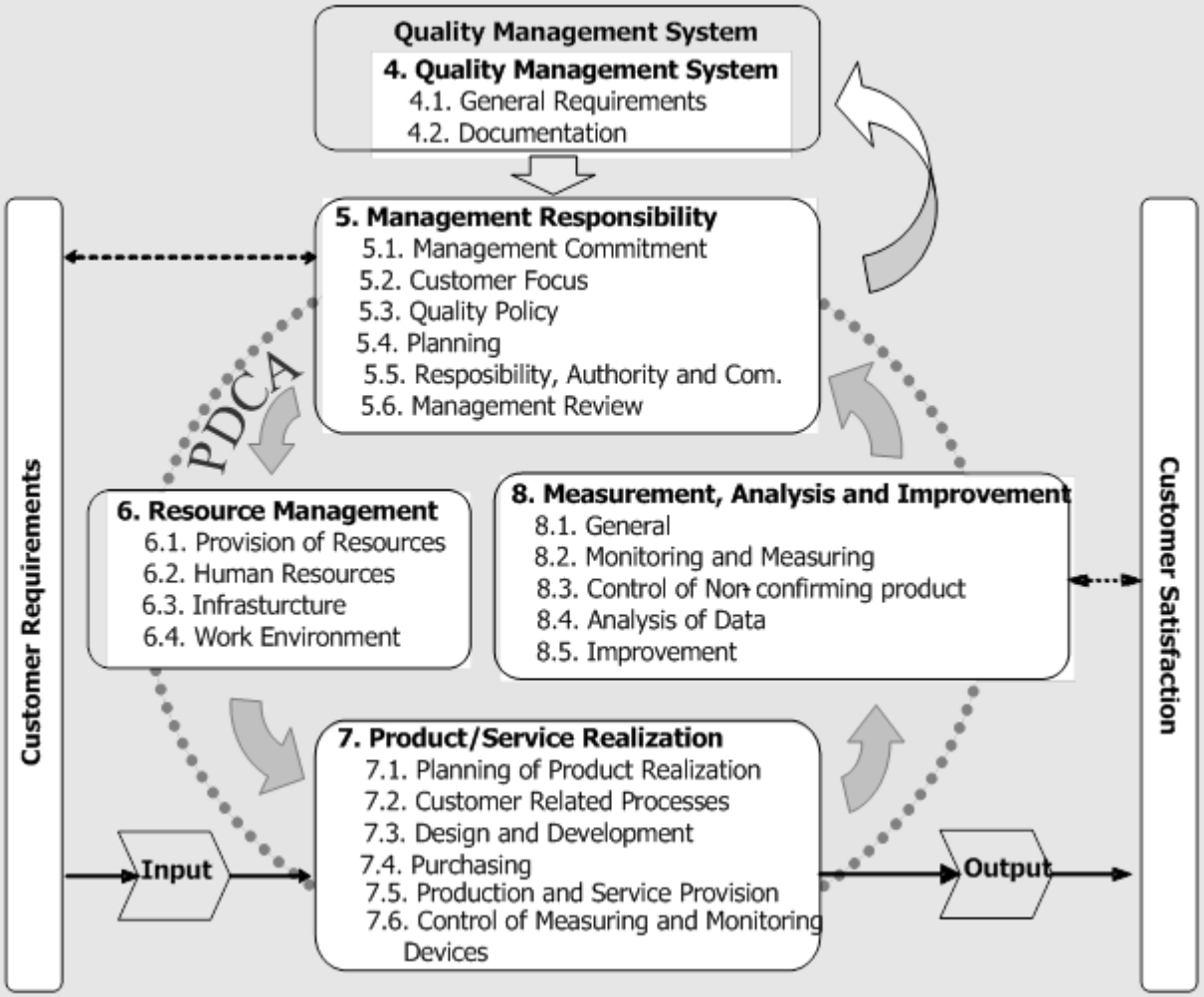


Control of records

The standard requires records *to be established and maintained to provide evidence of conformity to requirements and the effective operation of the quality management system.*

- Customer complaints
- Warranty claims
- Failure analysis reports
- Process capability studies
- Service reports
- Concessions
- Change requests
- Subcontractor assessments
- Performance analysis
- Deviations and waivers
- Contract change records
- Quality cost data
- External quality audit records

Clause 5.-Management responsibility



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6. Quality Planning

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HOW TO MANAGE FOR QUALITY: THE JURAN TRILOGY

Quality planning	Quality control	Quality improvement
Establish quality goals	Evaluate actual performance	Prove the need
Identify who the customers are	Compare actual performance with quality goals	Establish the infrastructure
Determine the needs of the customers	Act on the difference	Identify the improvement projects
Develop product features that respond to customers' needs		Establish project teams
Develop processes able to produce the product features		Provide the teams with resources, training, and motivation to: Diagnose the causes Stimulate remedies
Establish process controls; transfer the plans to the operating forces		Establish controls to hold the gains

Quality Planning Process

•“Quality planning,” as used here, is a structured process for developing products (both goods and services) that ensures that customer needs are met by the final result. The tools and methods of quality planning are incorporated along with the technological tools for the particular product being developed and delivered.

Quality planning steps;

A. Establish the project
B. Identify the customers
C. Discover the customer needs
D. Develop the product
E. Develop the process
F. Develop the controls and transfer to operations

A. Establish the Project

A quality planning project is the organized work needed to prepare an organization to deliver a new or revised product, following the steps associated with quality planning. Generally speaking, the following activities are associated with establishing a quality planning project:

- Identify which projects are required to fulfill the organization's strategy.
- Prepare a mission statement for each project.
- Establish a team to carry out the project.
- Plan the project.

B. Identify the Customers

• This step may seem unnecessary; of course, the planners and designers know who their customers are: the driver of the automobile, the depositor in the bank account, the patient who takes the medication. But these are not the only customers—not even necessarily the most important customers.

• Customers comprise an entire cast of characters that needs to be understood fully. Generally, there are two primary groups of customers: the *external customers*—those outside the producing organization; and the *internal customers*—those inside the producing organization.

C. Discover the customer needs

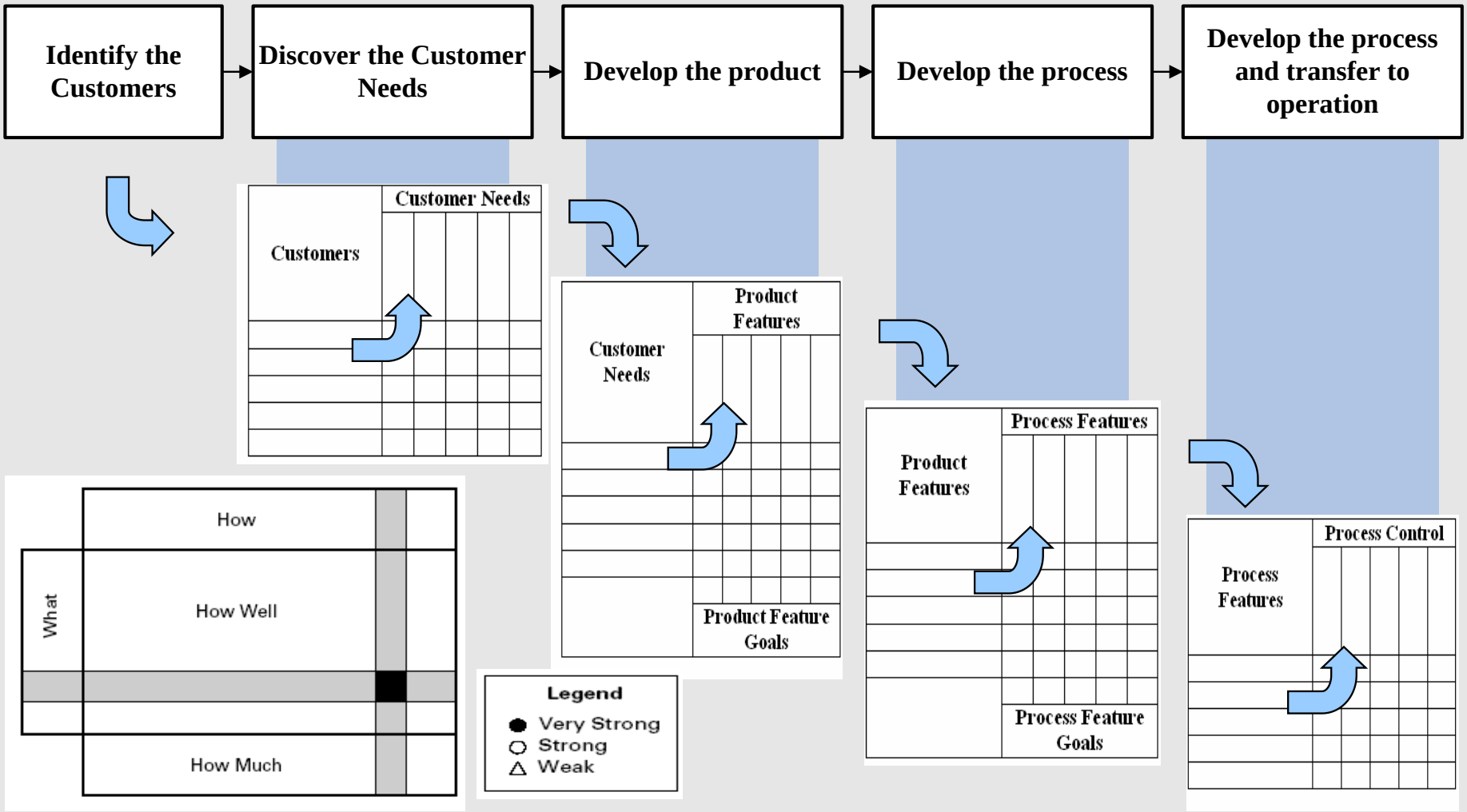
The third step of quality planning is to discover the needs of both internal and external customers for
the product. Some of the key activities required for effective discovery of customer needs include
-Plan to collect customers' needs.
-Collect a list of customers' needs in their language.
-Analyze and prioritize customers' needs.
-Translate their needs into "our" language.
-Establish units of measurement and sensors.

Quality Planning Spreadsheets.

•Quality planning generates a large amount of information that is both useful and necessary, but without a systematic way to approach the organization and analysis of this information, the planning team may be overwhelmed by the volume and miss the message it contains.

•Although planners have developed various approaches for organizing all this information, the most convenient and basic planning tool is the *quality planning spreadsheet.* The spreadsheet is a highly versatile tool that can be adapted to a number of situations.

Spreadsheets in quality planning.



Generic planning spreadsheet.

Customer needs spreadsheet for a magazine.

Customers	Customer Needs							
	Attractive	Informative/well-written articles	Catchy cover lines	Stable circulation	It sellls	Enough time	Material complete	No last minute changes
Readers	●	●	●					
Advertisers	●	○	●	●	●			
Printers						●	●	●
Typesetters						●	●	●
Color separators						●	●	●
Newsstand	●	○	●	●	●			

Legend

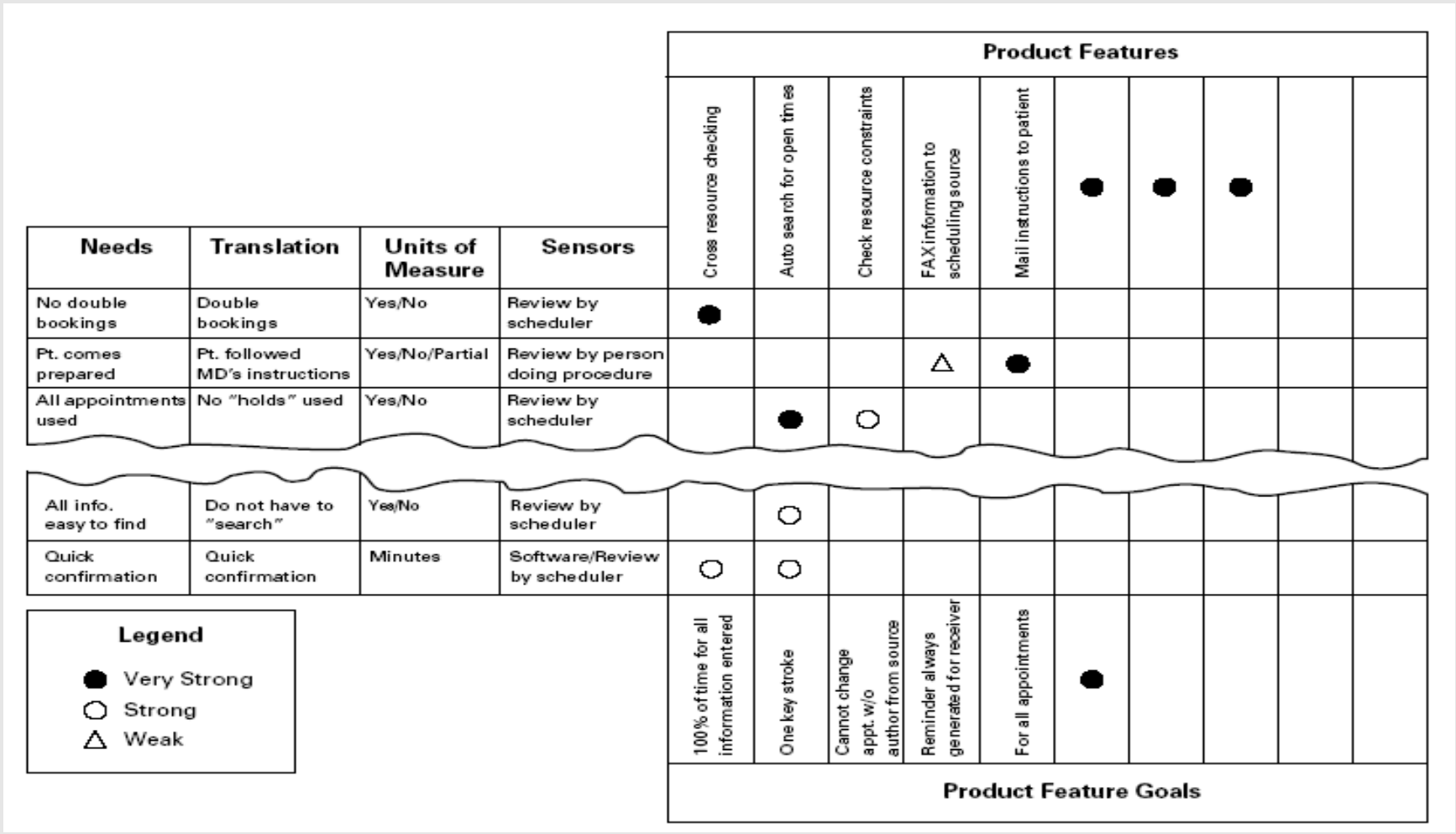
● Very Strong
○ Strong
△ Weak

D. Develop the product

• Once the customers and their needs are fully understood, we are ready to design the product that will meet those needs best. Product development is not a new function for a company. Most companies have some process for designing and bringing new products to market. In this step of the quality planning process, we will focus on the role of quality in product development and how that role combines with the technical aspects of development and design appropriate for a particular industry. Within product development, product design is a creative process based largely on technological or functional expertise.

There are six major activities in this step:
• Group together related customer needs.
• Determine methods for identifying product features.
• Select high-level product features and goals.
• Develop detailed product features and goals.
• Optimize product features and goals.
• Set and publish final product design.

Product design spreadsheet for outpatient appointment function.



Needs	Translation	Units of Measure	Sensors	Cross resource checking	Auto search for open times	Check resource constraints	FAX information to scheduling source	Mail instructions to patient					
				Product Features									
No double bookings	Double bookings	Yes/No	Review by scheduler	●									
Pt. comes prepared	Pt. followed MD's instructions	Yes/No/Partial	Review by person doing procedure				△	●					
All appointments used	No "holds" used	Yes/No	Review by scheduler		●	○							
All info. easy to find	Do not have to "search"	Yes/No	Review by scheduler		○								
Quick confirmation	Quick confirmation	Minutes	Software/Review by scheduler	○	○								
				100% of time for all information entered	One key stroke	Cannot change appt. w/o author from source	Reminder always generated for receiver	For all appointments	●				
				Product Feature Goals									

Legend

- ● Very Strong
- ○ Strong
- △ Weak

E. Develop the process

Once the product is developed, it is necessary to determine the means by which the product will be created and delivered on a continuing basis. These means are, collectively, the "process." "Process development" is the set of activities for defining the specific means to be used by operating personnel for meeting product quality goals.

The eleven major activities involved in developing a process are

1. *Review product goals.*
2. *Identify operating conditions.*
3. *Collect known information on alternate processes.*
4. *Select general process design.*
5. *Identify process features and goals.*
6. *Identify detailed process features and goals.*
7. *Design for critical factors and human error.*
8. *Optimize process features and goals.*
9. *Establish process capability.*
10. *Set and publish final process features and goals.*
11. *Set and publish final process design.*

Process design spreadsheet for a lawn care service.

		Process Features			
Product Feature	**Product Feature Goal**	Spray delivery capacity	Crew Size	Certified materials	Scheduling forecast on P.C. to determine to/from and work needed
Time to perform job	Less than one hour 100 percent of time	○	●		●
Guaranteed appointment time	99 percent of jobs within 15 minutes of appointment				●
All materials environmentally safe	All naturally occuring/no synthetics			●	
		10 gallons per minute	One person per 10,000 sq. ft. of yd.	100% approved by State Dept. of Agriculture	Forecast time always within 10 percent of actual
		Process Feature Goals			

Legend

- ● Very Strong
- ○ Strong
- △ Weak

F. Develop the controls and transfer to operations

In this step, planners develop controls for the processes, arrange to transfer the entire product plan to operational forces, and validate the implementation of the transfer. There are seven major activities in this step.

1. *Identify controls needed.*
2. *Design feedback loop.*
3. *Optimize self-control and self-inspection.*
4. *Establish audit.*
5. *Demonstrate process capability and controllability.*
6. *Plan for transfer to operations.*
7. *Implement plan and validate transfer.*

Once planning is complete, these plans are placed in the hands of the operating departments. It then becomes the responsibility of the operational personnel to manufacture the goods or deliver the service and to ensure that quality goals are met precisely and accurately. They do this through a planned system of quality control.

Control spreadsheet.

	PROCESS CONTROLS						
PROCESS FEATURE	CONTROL SUBJECT	SENSOR	GOAL	MEASURE-MENT FREQUENCY	SAMPLE SIZE	CRITERION	RESPONS-IBILITY
PROCESS FEATURE 1							
PROCESS FEATURE 2							
• • •							
WAVE SOLDER	SOLDER TEMPER-ATURE	THERMO-COUPLE	505°F	CONTIN-UOUS	N/A	≥ 510°F, DECREASE HEAT; 500°F, INCREASE HEAT	OPERATOR
	CONVEYOR SPEED	FT/MIN METER	4.5 FT/MIN	1/HOUR	N/A	≥ 5 FT/MIN, REDUCE SPEED; ≤ 4 FT/MIN, INCREASE SPEED	OPERATOR
	ALLOY PURITY	LAB. CHEM. ANALYSIS	1.5% MAX TOTAL CONTAMIN-ANTS	1/MONTH	15 GRAMS	≥ 1.5%, DRAIN BATH, REPLACE SOLDER	PROCESS ENGINEER

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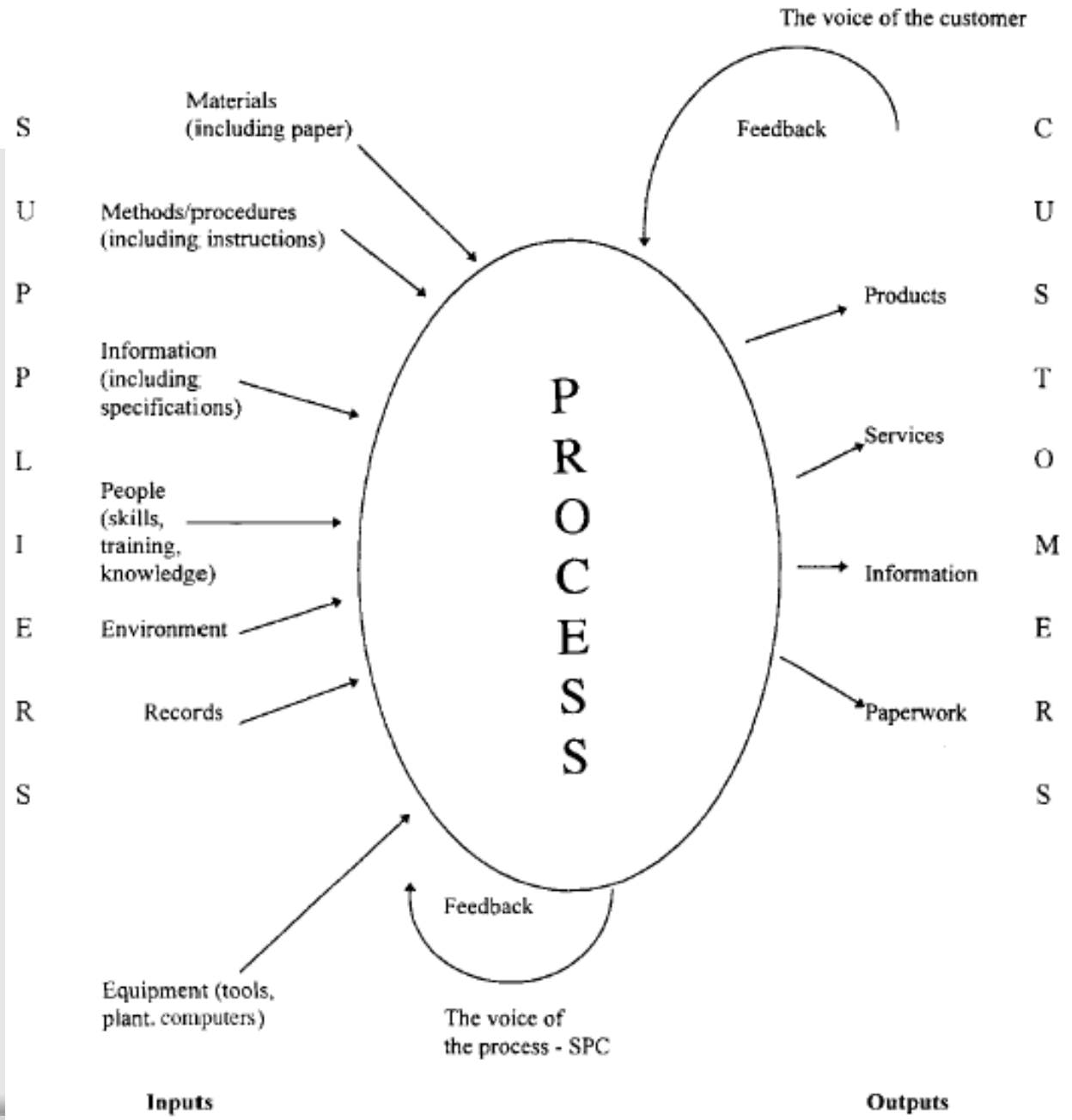
7. Process Management

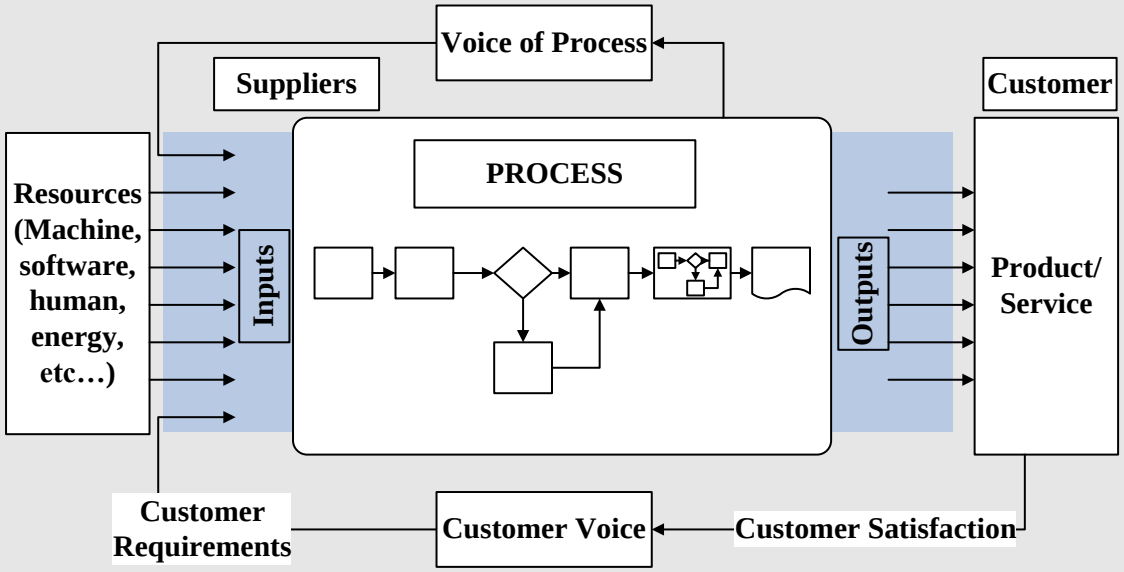
Dr. Ali Coşkun DALGIÇ

Process


The voice of the customer
Materials (including paper)
Feedback
SUPPLIERS
CUSTOMERS
Methods/procedures (including instructions)
Products
Information (including specifications)
PROCESS
Services
People (skills, training, knowledge)
Information
Environment
Paperwork
Records
Feedback
Equipment (tools, plant, computers)
The voice of the process - SPC
Inputs
Outputs

Process Management

Process management is the ensemble of activities of planning and monitoring the performance of a process, especially in the sense of business process, often confused with reengineering. Process Management is the application of knowledge, skills, tools, techniques and systems to define, visualize, measure, control, report and improve processes with the goal to meet customer requirements profitably.



The PM Methodology

A PM effort is initiated when executive management selects key processes, identifies owners and teams, and provides them with process mission statements and goals. After the owners and team are trained in process methodology, they work through the three phases of PQM methodology: planning, transfer, and operational management.

The planning phase, in which the process design (or redesign) takes place, involves five steps:

1.Defining the present process.
2.Determining customer needs and process flow.
3.Establishing process measurements.
4.Conducting analyses of measurement and other data.
5.Designing the new process. The output is the new process plan.

Process Management

Some Quality Processes

- Market Research and Customer Relation
- Internal Communications
- Document and record Control
- Planning
- Resources Management
- Product Design
- Food Manufacturing
- Purchasing
- Internal Audit
- Data Analysis
- Maintenance of measurement's and process equipments
- Calibration of measurement's equipment

Prerequisite Programs

- Construction and lay-out of buildings and associated utilities
- Lay-out of premises, including workspace and employee facilities
- The suitability of equipment and its accessibility for cleaning, maintenance and preventative maintenance
- Supplies of air, water, energy and other utilities
- Supporting services, including waste and sewage disposal
- Cleaning and sanitizing
- Pest control
- Personnel hygiene
- Measures for the prevention of cross contamination
- Management of purchased materials (e.g. raw materials, ingredients, chemicals and packaging), and supplies

Transferring the New Process Plan to Operations

The transfer phase consists of three steps:

(1) planning for implementation problems,

(2) planning for implementation action, and

(3) deploying the new process plan.

Operational Management Phase: Managing the New Process.

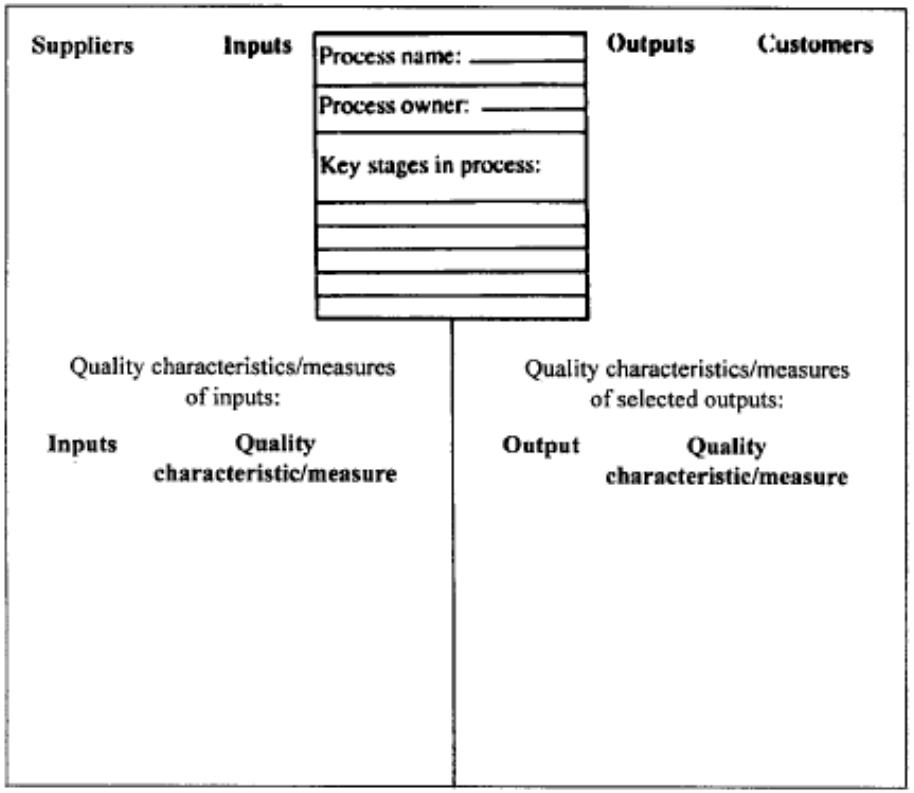
The Operational Management Phase begins when the process is put into operation. The major activities in operational management are:

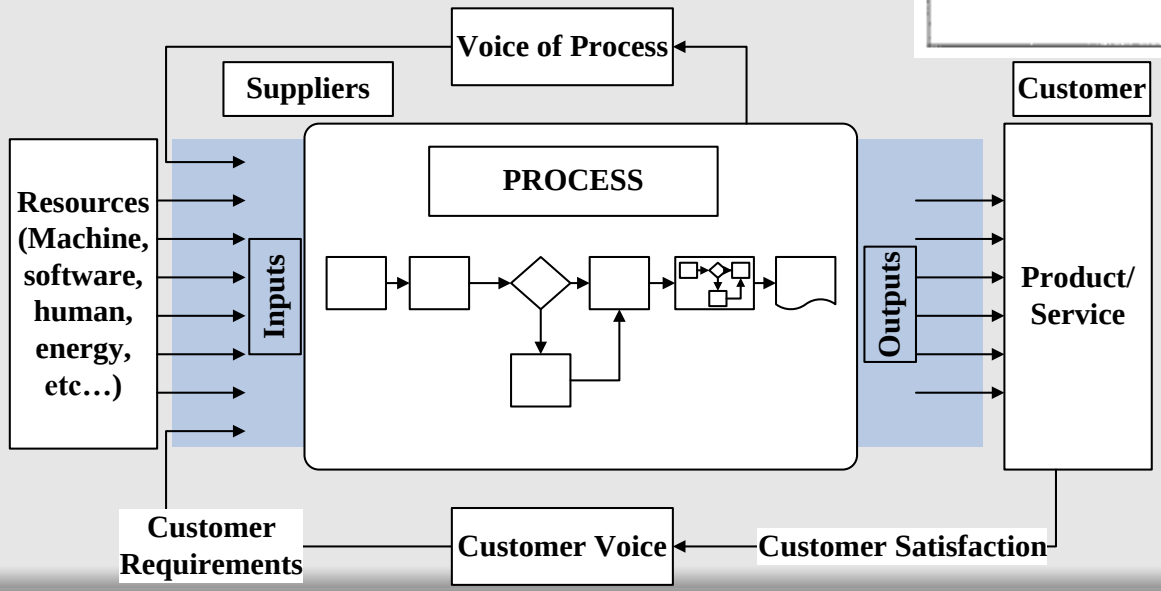
(1) process quality control,

(2) process quality improvement, and

(3) Periodic process review and assessment.

Describing the boundary of a process



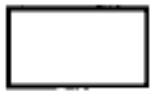


Process mapping and flowcharting

- Process mapping and flowcharting are very important first steps in improving a process. The flowchart ‘pictures’ will assist an individual or team in acquiring a better understanding of the system or process under study than would otherwise be possible. Gathering this knowledge provides a graphic definition of the system and the scope of the improvement effort. Process mapping, is a *communication* tool that helps an individual or an improvement team understand a system or process and identify opportunities for improvement.

Symbols used in flow diagramming.

These basic symbols are arranged to show the actual sequence of steps in a process, running consistently from top to bottom or left to right on the page. As we have seen, decision diamonds can lead us to branch back and repeat an earlier step.



The *activity symbol* is a rectangle that indicates a single step in the process. A brief description of the activity is shown inside the rectangle.

The *decision symbol* is a diamond that designates a decision or branch point in the process. The description of the decision or branch is written inside the symbol, usually in the form of a question. The answer to the question determines the path that will be taken out of the decision symbol. Each path is labeled to correspond to an answer.

The *terminal symbol* is a rounded rectangle that identifies the beginning or the end of a process. "Start" or "End" is shown inside the symbol.

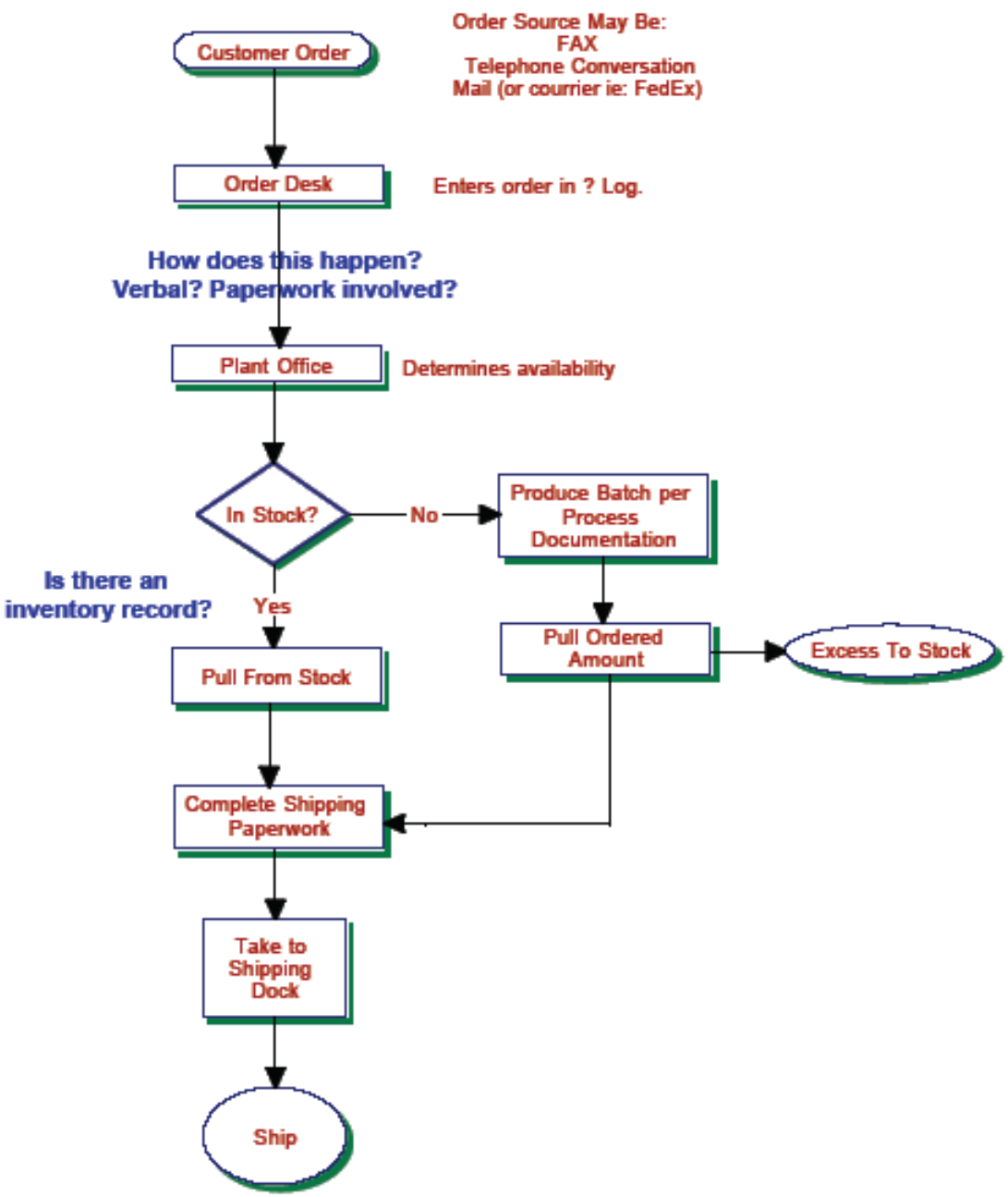
Flow lines are used to represent the progression of steps in the sequence. The arrowhead on the flow line indicates the direction of the process flow.

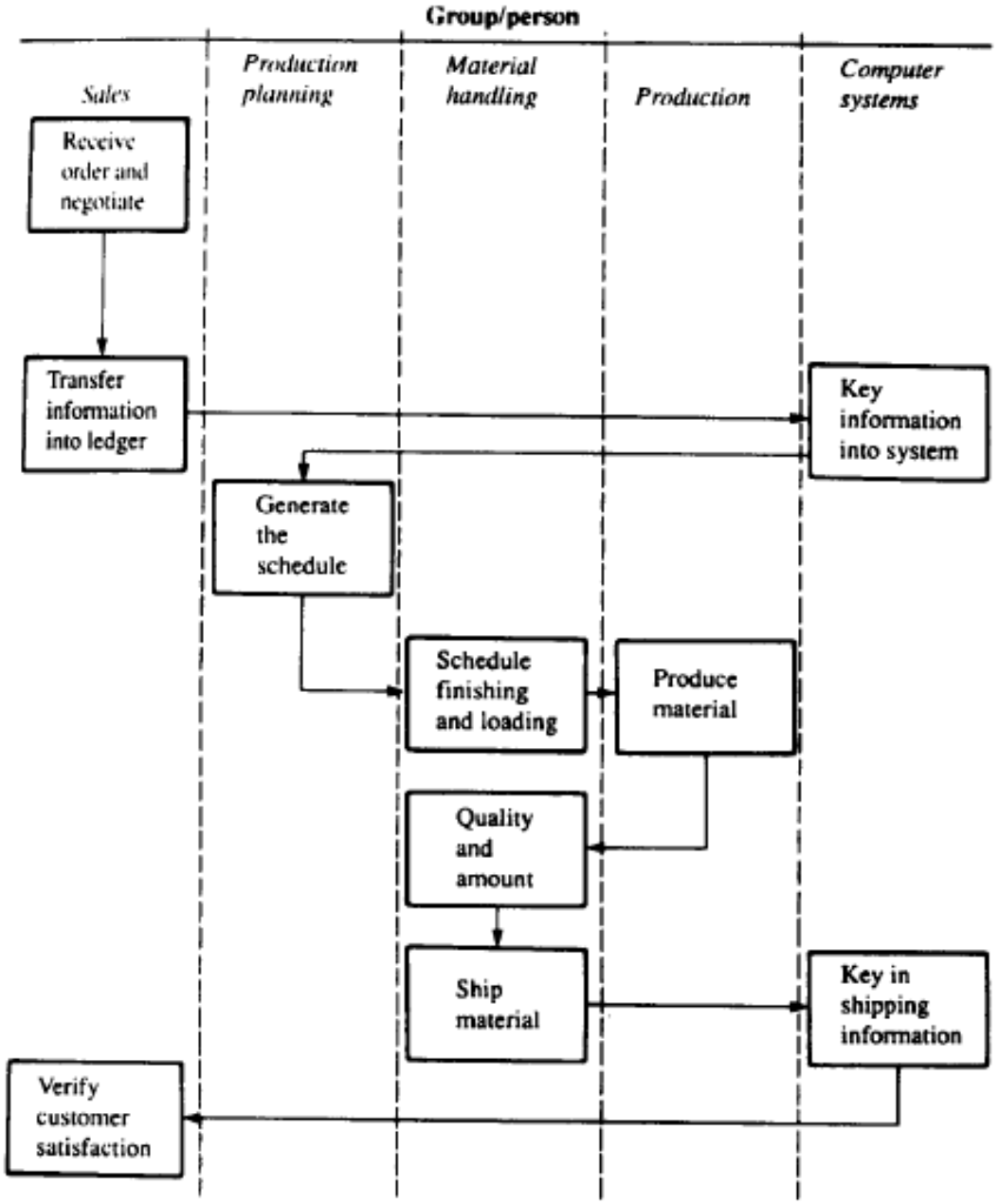
The *document symbol* represents written information pertinent to the process. The title or description of the document is shown inside the symbol.

The *data base symbol* represents electronically stored information pertinent to the process. The title or description of the data base is shown inside the symbol.

The *connector* is a circle used to indicate a continuation of the flow diagram. A letter or number is shown inside the circle. This same letter or number is used in a connector symbol on the continued flow diagram to indicate how the processes are connected.

Order Flow


Customer Order
Order Source May Be:
FAX
Telephone Conversation
Mail (or courrier ie: FedEx)
Order Desk
Enters order in ? Log.
How does this happen?
Verbal? Paperwork involved?
Plant Office
Determines availability
In Stock?
No
Produce Batch per Process Documentation
Is there an inventory record?
Yes
Pull Ordered Amount
Excess To Stock
Pull From Stock
Complete Shipping Paperwork
Take to Shipping Dock
Ship


Group/person
Sales
Production planning
Material handling
Production
Computer systems
Receive order and negotiate
Transfer information into ledger
Key information into system
Generate the schedule
Schedule finishing and loading
Produce material
Quality and amount
Ship material
Key in shipping information
Verify customer satisfaction

Process analysis

A flowchart is a picture of the steps used in performing a function. This function can be anything from a chemical process step to accounting procedures, even preparing a meal. Flowcharts provide excellent documentation and are useful trouble shooting tools to determine how each step is related to the others. By reviewing the flowcharts it is often possible to discover inconsistencies and determine potential sources of variation and problems. For this reason, flowcharts are very useful in process improvement when examining an existing process to highlight the problem area. A group of people, with knowledge about the process, should follow the simple steps:

- Draw flowcharts of the existing process, 'as is'.
- Draw charts of the flow the process could or should follow, 'to be'.
- Compare the two sets of charts to highlight the sources of the problems or waste, improvements required, and changes necessary.

Process analysis

- A critical examination of the first set of flowcharts is often required, using a questioning technique, which follows a well-established sequence to examine:

	the *purpose* for which the *place* at which the *sequence* in which the *people* by which the *method* by which	} the activities are undertaken,
with a view to	{ eliminating combining rearranging or simplifying	} those activities.

- Kipling's Law

Inputs	*Resources*	*Process*	*Constraints*	*Outputs*
What are the inputs?	What resources are required?	What tasks are performed?	What are the constraints?	What are the outputs?
Where do they come from?	Where do they come from?	Where are they performed?	Where in this process are they applied?	Where do they go?
Who supplies them?	Who supplies them?	Who performs the tasks?	Who imposes the constraints?	Who receives them?
How are they supplied?	How are they supplied?	How are the tasks performed?	How are they addressed?	How are they supplied?
When are they supplied?	When are they supplied?	When are the tasks performed?	When do they apply?	When are they supplied?
Why are they needed?	Why are they needed?	Why are the tasks performed?	Why are the constraints necessary?	Why are they needed?

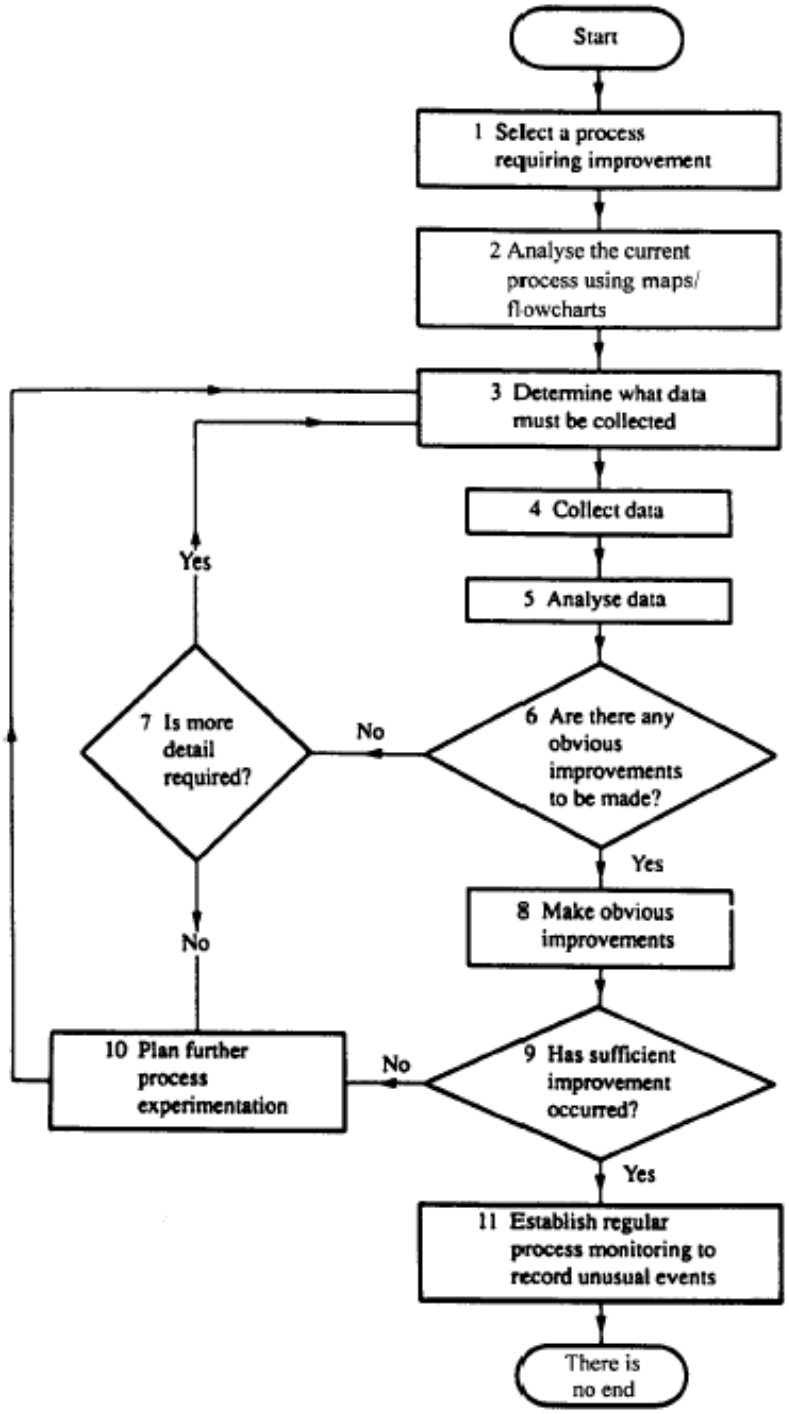
The questions which need to be answered in full are:

Purpose:	What is actually done? (or What is actually achieved?)	*Eliminate* unnecessary parts of the job.
	Why is the activity necessary at all?	
	What else might be or should be done?	
Place:	Where is it being done?	*Combine* wherever possible and/or *rearrange* operations for more effective results or reduction in waste.
	Why is it done at that particular place?	
	Where else might it or should it be done?	
Sequence:	When is it done?	
	Why is it done at that particular time?	
	When might or should it be done?	
People:	Who does it?	
	Why is it done by that particular person?	
	Who else might or should do it?	
Method:	How is it done?	*Simplify* the operations
	Why is it done in that particular way?	
	How else might or should it be done?	

Steps of Process Analysis:

- *Document and map/flowchart the process – making visible the invisible through mapping/flowcharting is the first crucial step that helps an organization see the way work really is done and not the way one thinks or believes it should be done. Seeing the process 'as is' provides a baseline from which to measure, analyse, test and improve.*
- *Identify process customers and their requirements; establish effectiveness measurements – recognizing that satisfying the external customer is a shared purpose, all internal and external suppliers need to know what customers want and how well their processes meet customer expectations.*
- *Analyse the process; rank problems and opportunities – collecting supporting data allows an organization to weigh the value each task adds to the total process, to select areas for the greatest improvement and to spot unnecessary work and points of unclear responsibility.*
- *Identify root causes of problems; establish control systems – clarifying the source of errors or defects, particularly those that cross department lines, safeguards against quick-fix remedies and assures proper corrective action.*
- *Develop implementation plans for recommended changes – involving all stakeholders, including senior management, in approval of the action plan commits the organization to implementing change and following through the 'to be' process.*
- *Pilot changes and revise the process – validating the effectiveness of the action steps for the intended effect leads to reinforcement of the 'to be' process strategy and to new levels of performance.*
- *Measure performance using appropriate metrics – once the processes have been analysed in this way, it should be possible to develop metrics for measuring the performance of the 'to be' processes, sub-processes, activities, and tasks. These must be meaningful in terms of the inputs and outputs of the processes, and in terms of the customers of and suppliers.*

Steps of Process Analysis:



FE 422 FOOD PRODUCTION MANAGEMENT

8. Quality Cost

Dr. Ali Coşkun DALGIÇ

EVOLUTION OF QUALITY AND COSTS

- During the 1950s there evolved numerous quality-oriented staff departments. The heads of these new departments were faced with “selling” their activities to the company managers. Because the main language of those managers was money, the concept of studying quality-related costs provided the vocabulary to communicate between the quality staff departments and the company managers.

- ***The Language of Money Is Essential.*** Money is the basic language of upper management. Despite the prevalence of estimates, the figures provide upper managers with information showing the overall size of the quality costs, their prevalence in areas beyond manufacture, and the major areas for potential improvement. Without the quality cost figures, the communication of such information to upper managers is slower and less effective.

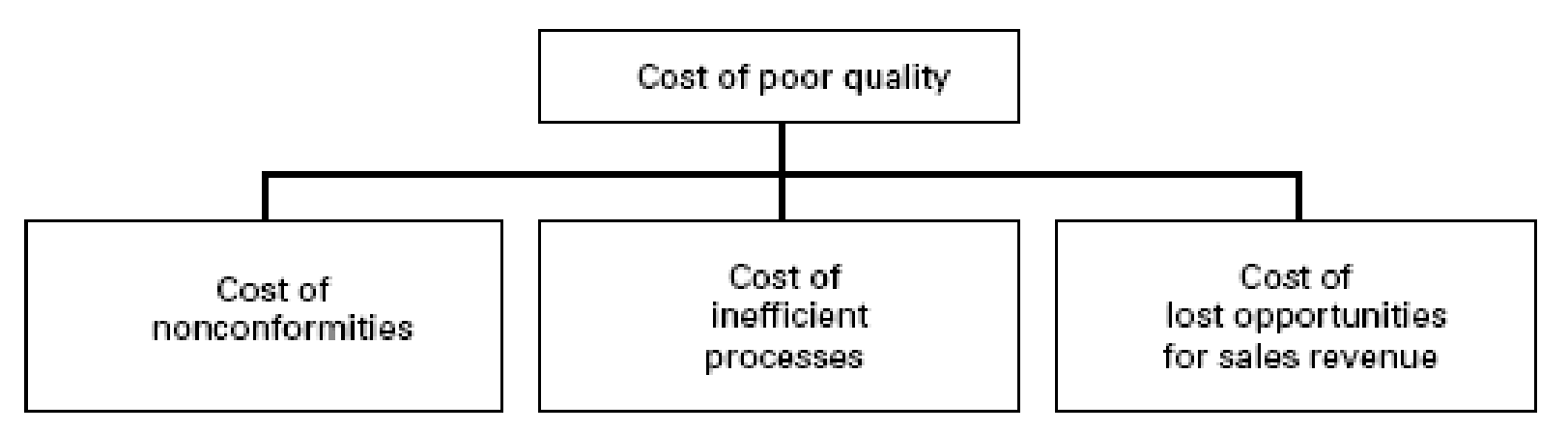
- ***The Meaning of "Quality Costs."*** The term "quality costs" has different meanings to different people. Some equate "quality costs" with the costs of poor quality (mainly the costs of finding and correcting defective work); others equate the term with the costs to attain quality; still others use the term to mean the costs of running the Quality department. In this handbook, the term "quality costs" means the cost of poor quality.

- ***Quality Cost Measurement and Publication Does Not Solve Quality Problems.*** Some organizations evaluate the cost of poor quality and publish it in the form of a scoreboard in the belief that publication alone will stimulate the responsible managers to take action to reduce the costs. These efforts have failed. The realities are that publication alone is not enough. It makes no provision to identify projects, establish clear responsibilities, provide resources to diagnose and remove causes of problems, or take other essential steps. New organization machinery is needed to attack and reduce the high costs of poor quality

- ***Scope of Quality Costs Is Too Limited.*** Traditionally, the measurement of quality cost focuses on the cost of nonconformities, i.e., defects in the goods or services delivered to external and internal customers. These are often called external and internal failure costs. An important cost that is not measured is lost sales due to poor quality (this is called a “hidden cost” because it is not easily measured). Another omitted cost is the extra cost in processes that were producing conforming output but which are inefficient. These inefficiencies are due to excess product or process variability (even though within specification limits) or inefficiencies due to redundant or non-value-added process steps.

CATEGORIES OF QUALITY COSTS

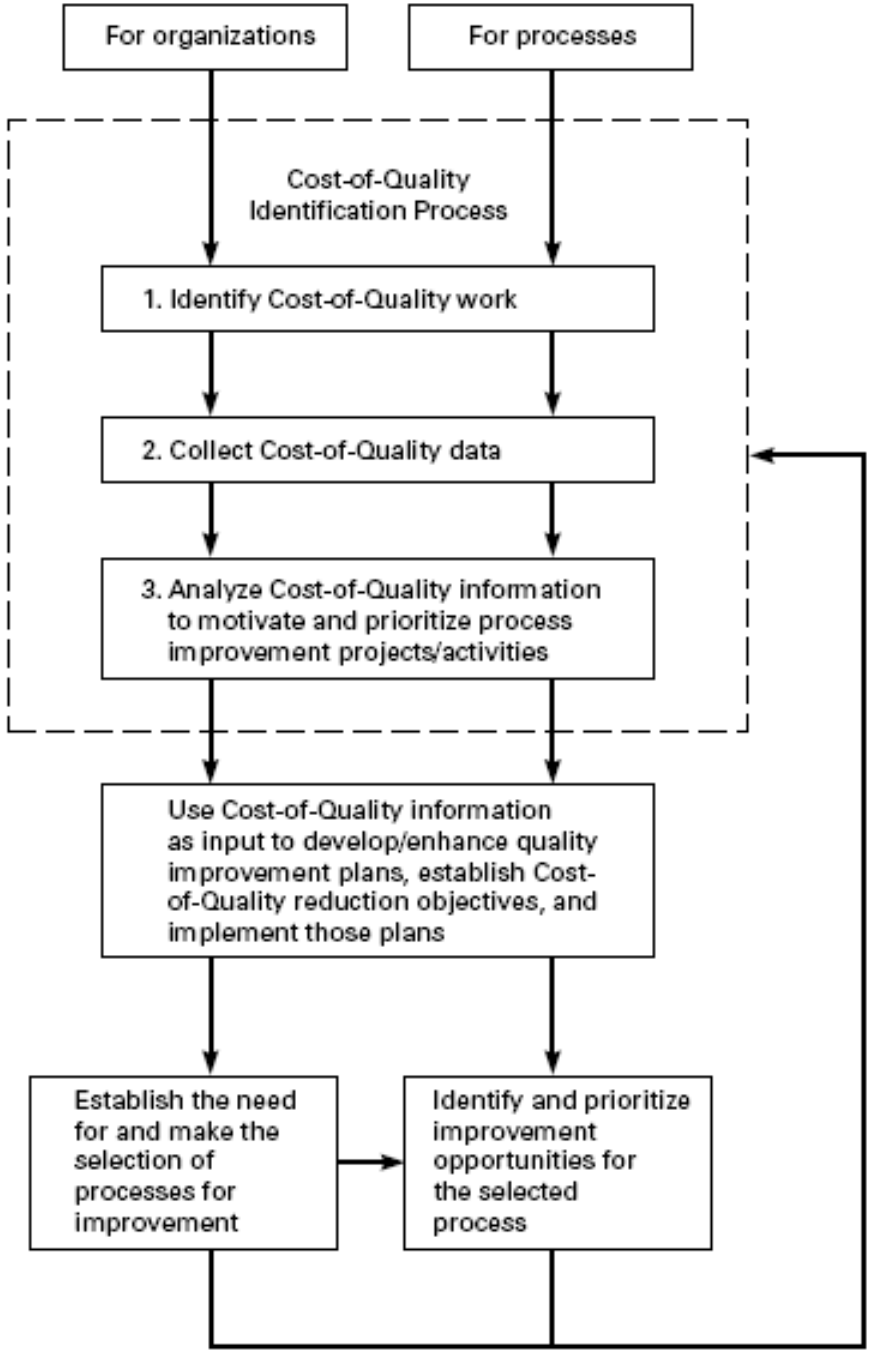
- **Internal Failure Costs.** These are costs of deficiencies discovered before delivery which are associated with the failure (nonconformities) to meet explicit requirements or implicit needs of external or internal customers. Also included are avoidable process losses and inefficiencies that occur even when requirements and needs are met. These are costs that would disappear if no deficiencies existed.



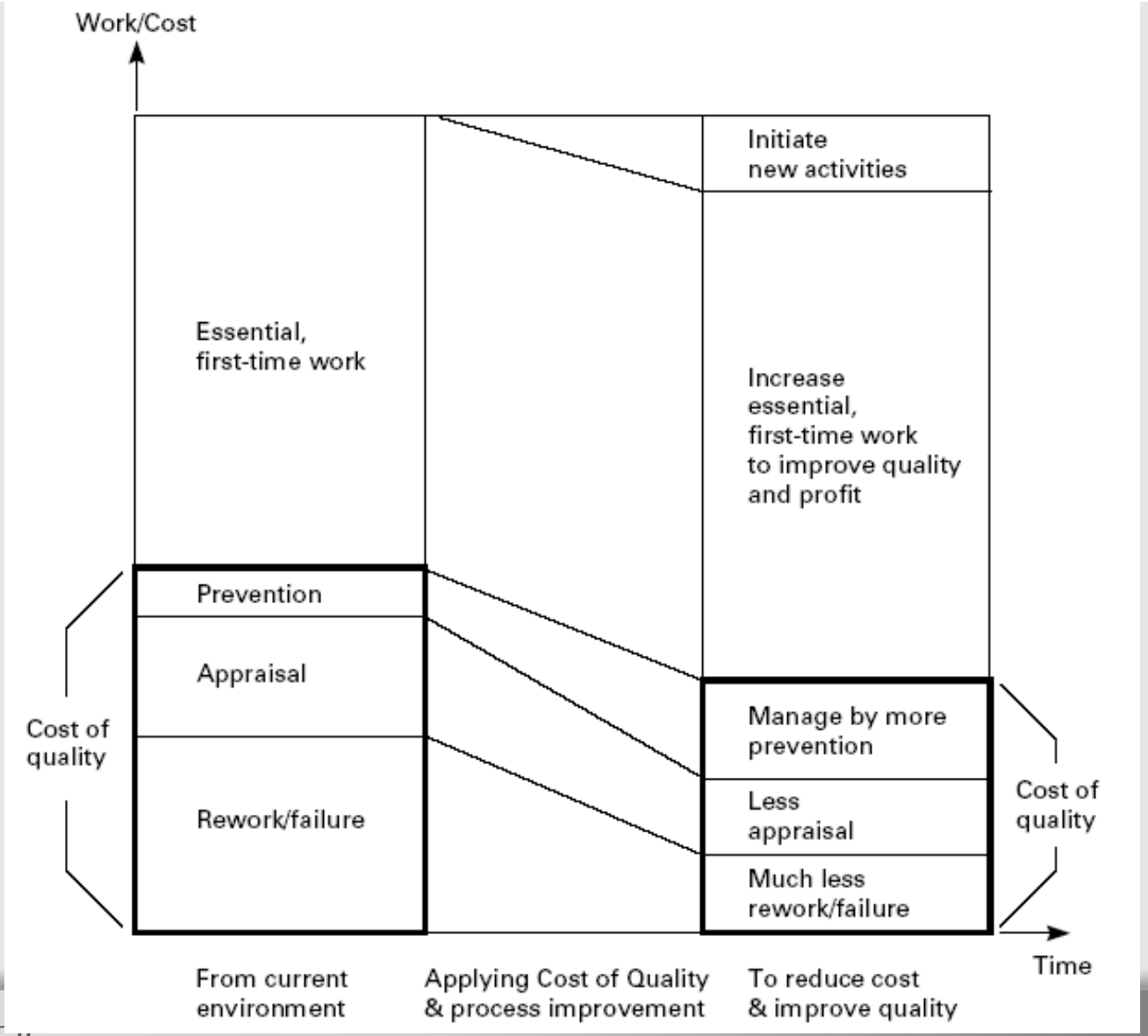
CATEGORIES OF QUALITY COSTS

- **External Failure Costs.** These are costs associated with deficiencies that are found after product is received by the customer. Also included are lost opportunities for sales revenue. These costs also would disappear if there were no deficiencies.
- **Appraisal Costs.** These are the costs incurred to determine the degree of conformance to quality requirements.
- **Prevention Costs.** These are costs incurred to keep failure and appraisal costs to a minimum.

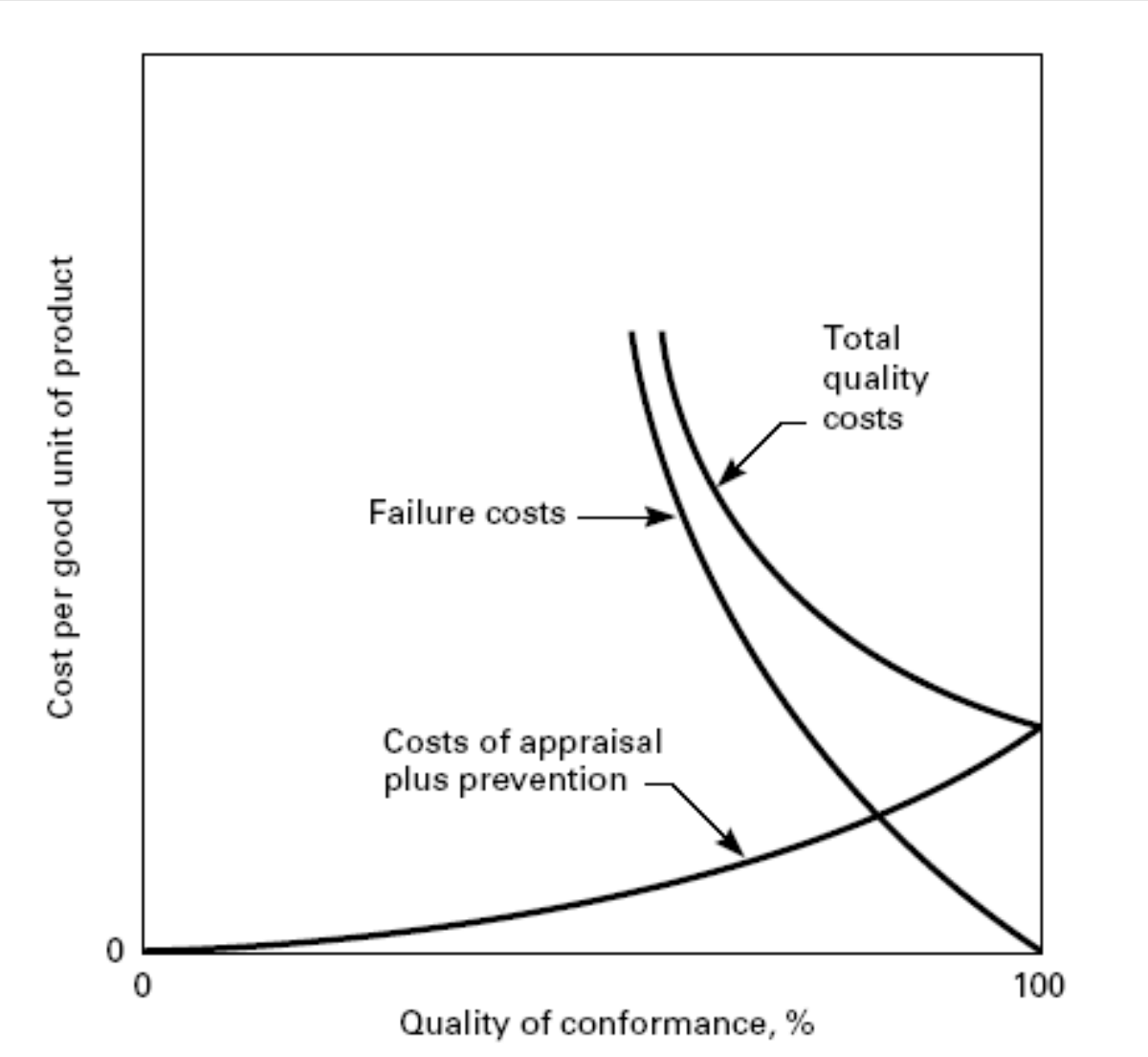
Cost of quality and quality improvement.

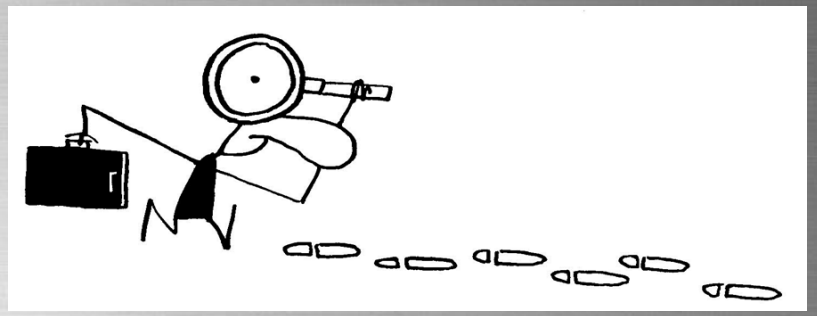


Effects of identifying cost of quality.



Model for optimum quality costs





FE 322 FOOD PRODUCTION MANAGEMENT

9. Quality and safety audit systems

Dr. Ali Coşkun DALGIÇ

Types of Audit

(a) First party audit

It's the tool by which the "*business*" is monitoring adherence to the documented HACCP system. It provides detailed information about failures of the system and highlights the potentiality of improvement. The auditors are chosen within the company but not strictly related to the area, function or procedures being audited.

(b) Second party audit

It is the tool through which the customer can directly evaluate if the process/product of his supplier satisfies its request. In this case the auditor usually belongs to the customer's staff. Sometimes the supplier can choose one person among the personnel who can act as a "*representative*" of the customer. In many cases the customer is hiring an independent expert to do the Auditing for him.

Types of Audit

(c) Third party audit (*another pair of eyes*)

It is performed by agencies, independent of both customer and suppliers, recognised as competent to assess system against a standard. For quality management system, third party audit is carried out by internationally recognised agencies; it's volunteer and the company will achieve certification related to the quality standard met. Regulatory Audit complies with this type of audit.

(d) Vertical audit

It is used to look in depth a particular function or department. It permits to monitor the use of all relevant procedures as they are used to support this function or department.

(e) Horizontal audit

It is used to follow a process from the start to the end. This kind of audit would look at procedures as they support the process itself and is likely to span many different functions or departments. Audits or assessment leading to certification are likely to be horizontal.

Types of Audit

(f) Partial audit

It consists of an assessment of a part of the system. The partial audit goal may be focused on:

- selected components or areas of HACCP system;
- follow-up to previous full or partial audit;
- concerns detected through consumer complaints;
- company's HACCP system changes;

(g) Full audit

It consists of an assessment of both, prerequisite programmes and HACCP systems

Auditor

An auditor generally should be a person with abilities and deep knowledge on the subject. It is important that he will be able to show tact and ability to put Auditees at ease. He should also be a good listener and aware questioner. From the technical point of view he should have a suitable technical background to really understand the process being audited and of course some knowledge of quality management.

Audit procedure

Audit procedure

The audit procedure and the related forms belong to the HACCP system documents. It will include surveillance activities and checks on monitoring data to assure the respect of critical limits as well as systematic and independent measures (*control and test on products and processes*). The reason for that is to achieve objective evidence that the food processing plant own-checks-system complies with the standards. All the results will be filed in order to qualify and assure that the audit will be conducted on the basis of previously established rules, which will define methods, tools, frequency, responsibility and proper record keeping.

Audit procedure

Frequency of auditing

The frequency of auditing has to assure that the System will not loose efficacy with time. Therefore special audits out-of-schedule, should take place when there are changes related to raw material (*new supplier for example*) or to the product (*changes in processing conditions, purchase of new equipment, new packaging material, extra cleaning and sanitising, etc*). Other reasons for extra (out-of-schedule) audits are: change in storage conditions, consumer use, receipt of any information on a new hazard associated with the product, evidence or suspect of non compliance, previous audit findings, etc. Frequency is strictly related to the risks presented by a product and processes and to the ability of the establishment to adhere to its HACCP system. The risks of the establishment can be classified under three categories:

Audit procedure

Category I: includes all the factories whose process includes a “kill step” or other kind of process step, able to reduce or eliminate specific microbial contaminants. Many of the products are “ready-to-eat”. Therefore, the loss of control within these establishments could mean a significantly high health risk.

Examples:

- Pasteurisation, heat treatment, drying, freezing dairy products, and processed eggs
- Thermal processing of low acid /acidified low acid canned food
- Assembling, packaging and cooking of infant food

Audit procedure

Category II: includes the establishments whose process generally don't include any kill steps. The processing control doesn't minimise the potential hazards through proper sanitation or temperature control as in category I. So the quality of raw product entering has to be considered a crucial factor and requires a special consideration in order to permit manipulation without significantly increasing risk. In category II, specific handling and storage instructions are required in order to protect the consumer

Examples:

- Washing, grading, packing shell eggs
- Fresh cutting, modified atmosphere packaging vegetables
- Freezing vegetables
- Cutting, packaging cheese

Audit procedure

Category III: consists of establishments preparing products which do not pose significant health hazards and the food processing to which they are exposed represents little or no additional risk.

Examples:

- Thermal processing, aseptic processing high acid foods
- Maple processing
- Honey processing
- Freezing, drying, packaging fruits
- Drying, packaging vegetables

Audit procedure

Audit preparation

According to the HACCP plan there are certain activities that lead to a proper auditing. These activities constitute the “audit plan” and can be summarised as following:

Audit scope: There should be always a definition of the boundaries of an audit (*i.e. what is going to be audited*). It may depend by factors such as results of previous audits, establishment profile, consumer complaints and other information.

Identification of the Chief auditor and the team members (*if it is applicable*): The number of auditors required depends on the size of the company and the diversity of the functions carried out within the establishment. The audit team members are selected in relation to specified requirements (*training, experiences, etc*). They can belong to the plant staff or to an external structure. The auditors must be independent of the function and the department being audited. This is absolutely necessary to prevent conflict of interest.

Audit procedure

In order to avoid the possibility to obtain insufficient or incomplete data, the auditor/auditing team will choose and elaborate all necessary tools. This necessary documentation to facilitate the auditor's work and to document and record all results must include:

- **Check list** to evaluate HACCP system elements and elaborate a specific segment of the system;
- **forms** to record all findings collected;
- **forms** to document the objective evidence in order to support the auditors final conclusion

Audit

Opening meeting

It is necessary for the members of the audit team to be introduced to the management representatives so they can review together the key areas of the planned audit. This meeting allows the establishment of official communication links between the audit team and the management of the plant and confirms that the resources and facilities needed are available for the team. Furthermore it is the proper time and place when all necessary written prerequisite programmes and HACCP plans will be made available to the team.

Audit

Gathering information

The audit is necessary to obtain evidence that procedures, documents and other information describing HACCP system are kept up to date, are adequate in order to achieve the required food safety objectives and they meet regulatory requirements. For this reason, the auditor should conduct a series of activities such as questioning, observing, examining records etc.

Results

The data provided by audit, need to be analysed in order to discover trends and confirm improvements, to highlight difficulties in the application of procedures or in particular activities or step of the process, and finally to give right information on what types of corrective actions have being carried out and how long corrective actions take to be implemented

Closing meeting

The auditor will communicate all findings to the HACCP co-ordinator. Prior to preparing the audit report, the audit team will meet with management representatives and present the audit findings. In relation to the evaluation of non-conformities identified, the audit team will propose the Corrective Action request and the timetable to solve them. The auditor should be sure that the results of the audit are clearly understood.

Audit report

The audit report has to include the scope of the audit, the identification of the chief auditor and audit members, the identification of the establishment representatives, the identification of the reference documents against which the audit was conducted and of course the audit findings. The audit findings have to be supported by the "*evidence*". This means that the auditor has to report "*what*" and "*where*" he detected the non-conformity.

FE 322 FOOD PRODUCTION MANAGEMENT

10. Statistical process control

Dr. Ali Coşkun DALGIÇ

Statistical Process Control (SPC)

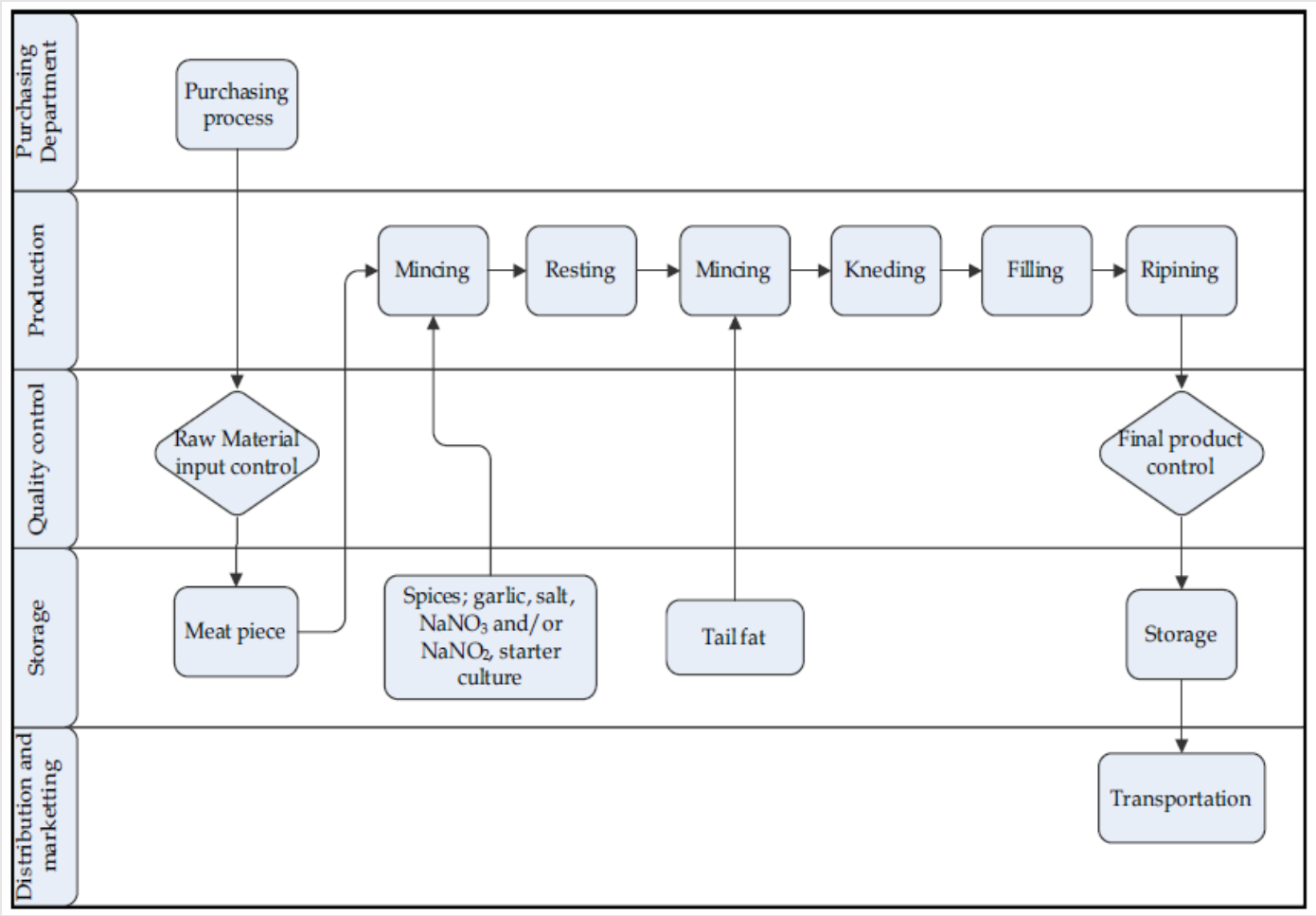
Statistical process control (SPC) is defined as the application of statistical techniques to control a process. SPC is concerned with quality of conformance. There are a number of tools available to the quality engineer that is effective for problem-solving process. The seven quality tools are relatively simple but very powerful tools which every quality engineer. The tools are:

- flow chart,
- run chart,
- process control chart,
- histograms,
- Pareto diagram,
- cause and effect diagram,
- and scatter diagram

Improvement of Food Safety and Quality by Statistical Process Control (SPC)

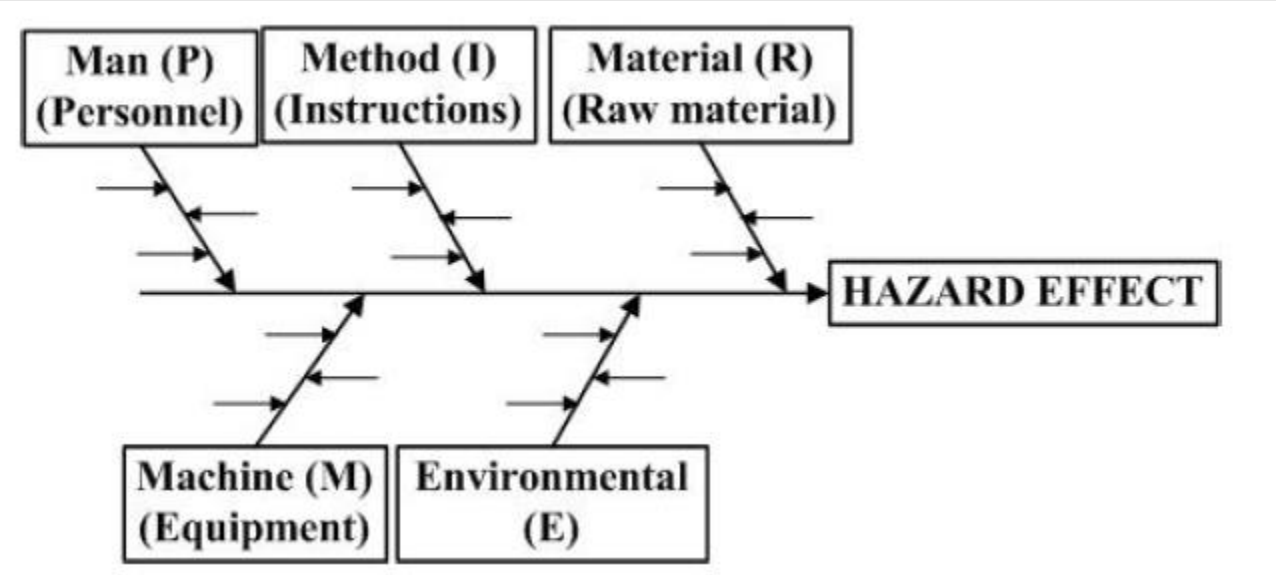
Flow charts;

Flow charts are defined as the graphical representation of the steps of in a process. Flow charts facilitate an analysis of the steps in a process to determine relationships between the steps.



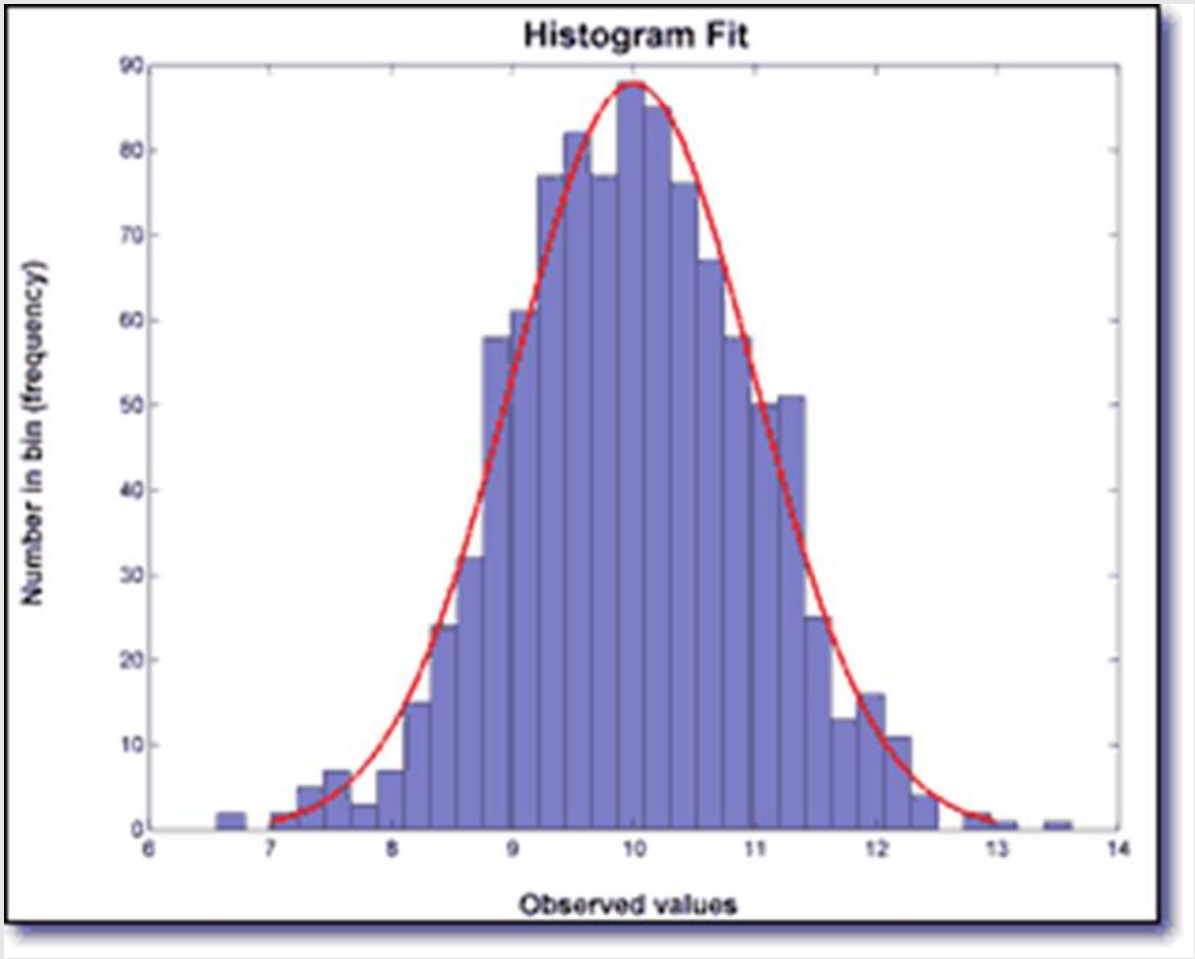
Cause and effect diagrams

Cause and effect diagrams (CED) are simple techniques for dissecting a problem or a process. CED identifies all possible relationships among input and output variables, that is, the five categories on the following skeleton (materials, machines, man, methods, and environment).



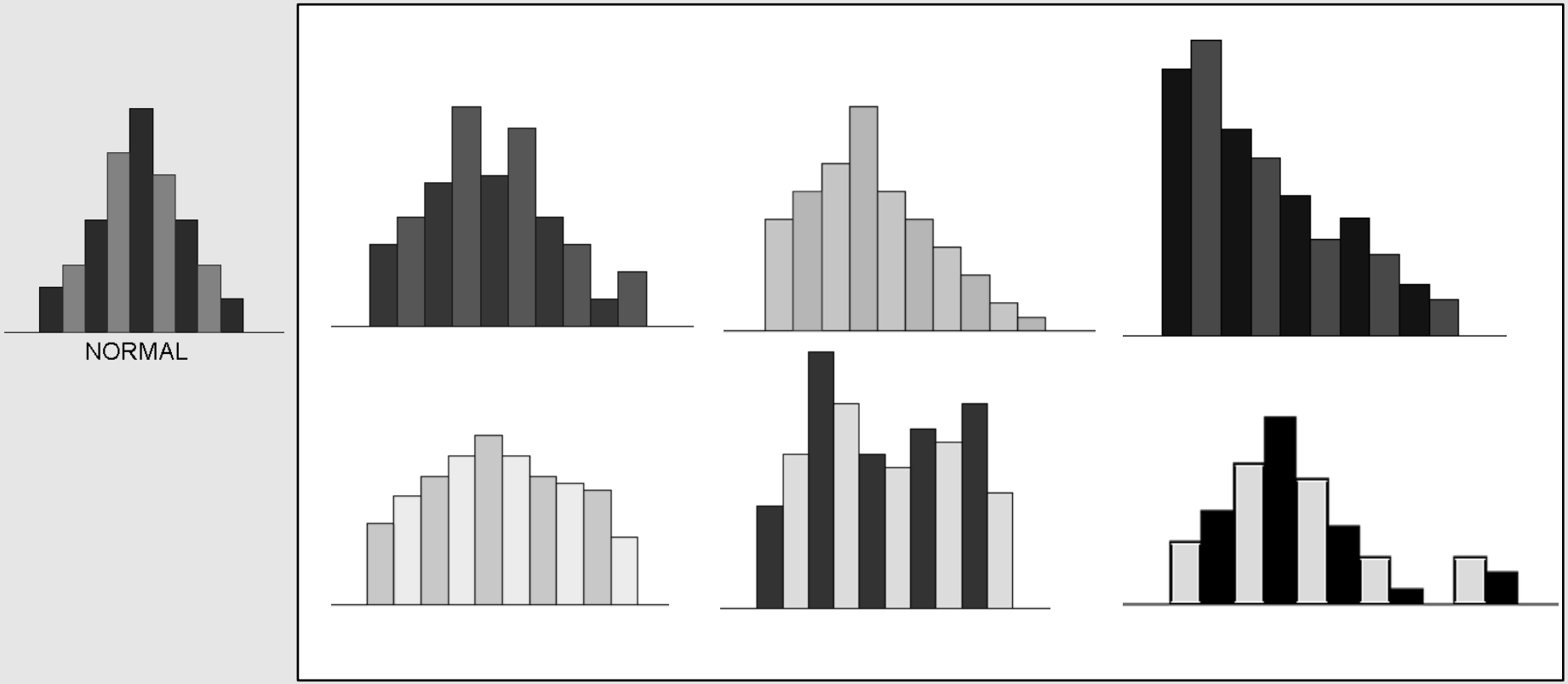
Histograms

A histogram is a bar chart showing the variation or distribution of the observations from a set of data.



Histograms

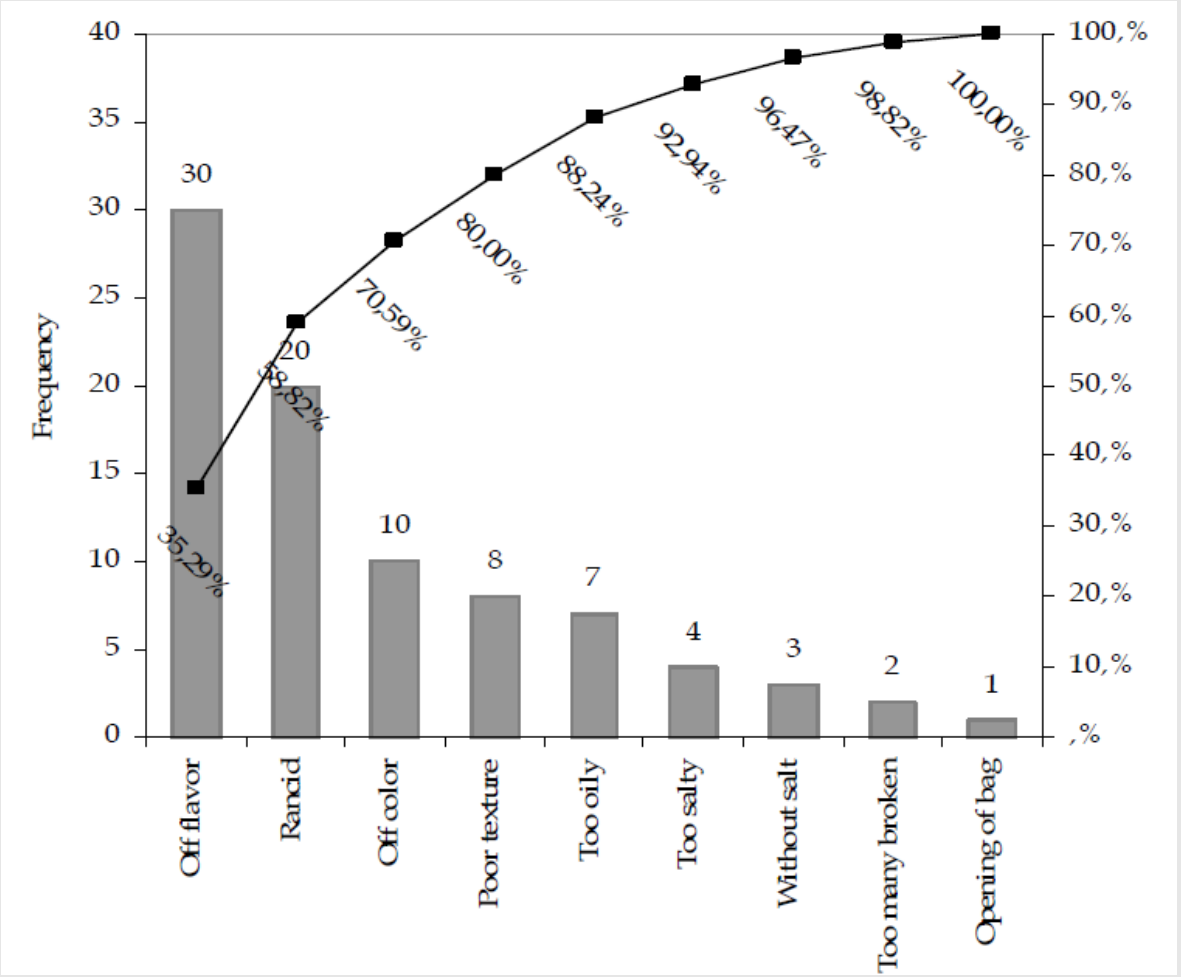
A histogram is a bar chart showing the variation or distribution of the observations from a set of data.



Improvement of Food Safety and Quality by Statistical Process Control (SPC)

Pareto charts

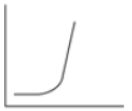
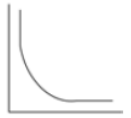
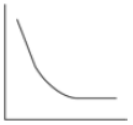
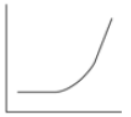
The pareto chart is a form of bar chart with each bar representing a cause of a problem and always arranged so that the most influential cause of a problem can be easily recognized, that is, arranging the problems in descending order. This information is helpful in focusing attention on the highest-priority category.



Improvement of Food Safety and Quality by Statistical Process Control (SPC)

Scatter diagrams

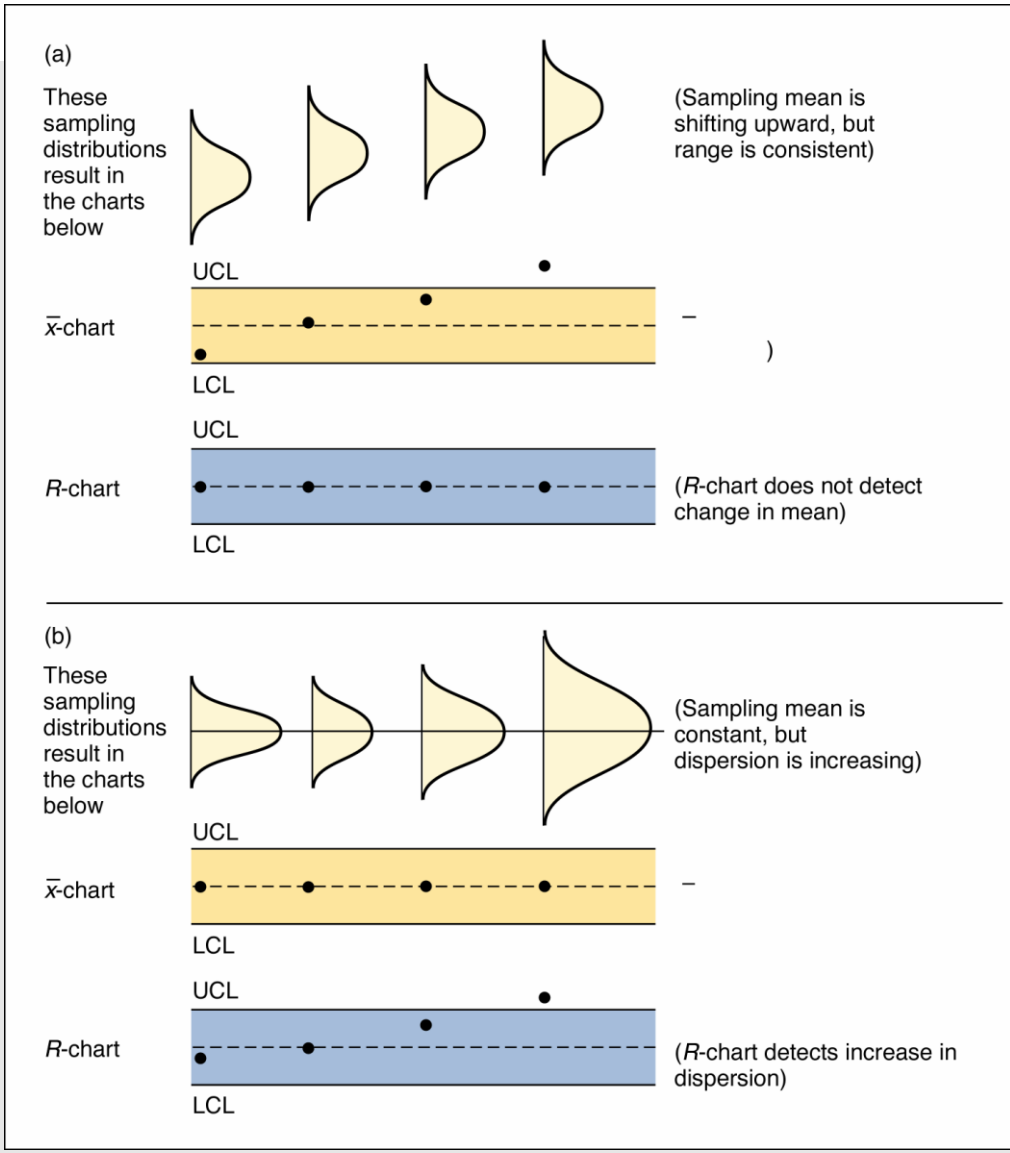
Scatter diagramming is a tool to study how different variables relate to each other or how they correlate. A scatter diagram demonstrates the results of a series of experiments which is conducted to document the relationship between the variables. Table 4. represents the mathematical models.

Expression	Mathematical models	Geometric shape
Sigmoidal (Gompertz)	$y = y_0 + ae^{-e^{-(\frac{x-x_0}{b})}}$	
Sigmoidal (Lojistic)	$y = y_0 + \frac{a}{1+(\frac{x}{x_0})^b}$	
Sigmoidal (Sigmoid)	$y = y_0 + \frac{a}{1+e^{-(\frac{x-x_0}{b})}}$	
Sigma (GAB)	$y = \frac{abcx}{(1-ax)(1-ax+abx)}$	
Polynomial (linear)	$y = y_0 + ax$	
Polynomial (Quadratic)	$y = y_0 + ax + bx^2$	
Polynomial (inverse first order)	$y = y_0 + \frac{a}{x}$	
Peak (Guassian)	$y = y_0 + ae^{\left[-0.5(\frac{x-x_0}{b})^2\right]}$	
Peak (Lorentzian)	$y = y_0 + \frac{a}{1+(\frac{x-x_0}{b})^2}$	
Exponential decay	$y = y_0 + ae^{-bx} + ce^{-dx}$	
Exponential growth	$y = y_0 + ae^{bx} + ce^{dx}$	

Process control charts

Variable control charts

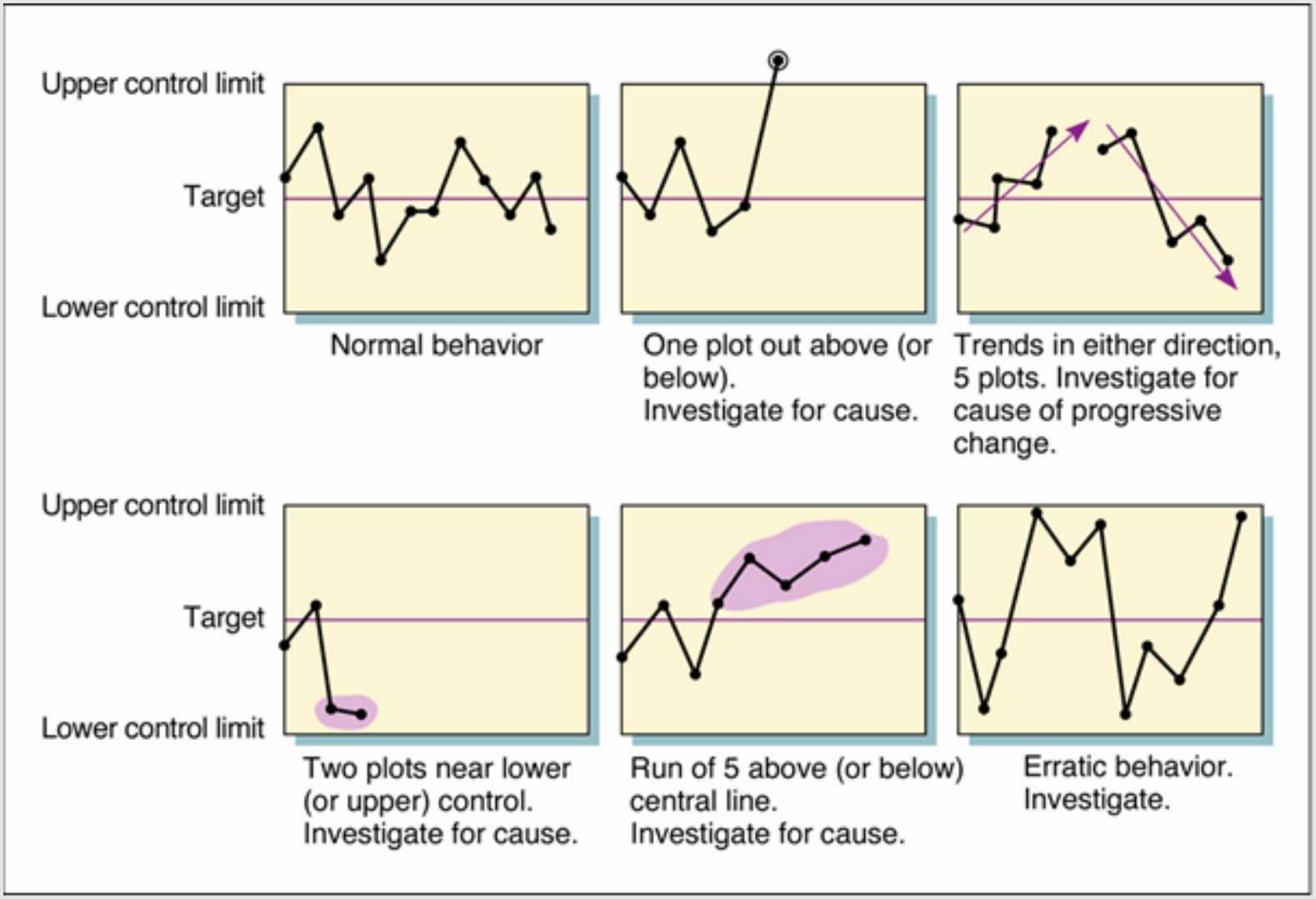
The primary function of a control chart is to determine which type of variation is present and whether adjustments need to be made to the process. Variables data are those data which can be measured on a continuous scale. Variable data are plotted on a combination of two charts- usually an x-bar (x) chart and a range (R) chart. The x-bar chart plots sample means. It is a measure of between-sample variation and is used to asses the centering and long term variation of the process. The range chart measure the within sample variation and asses the short term variation of the process.

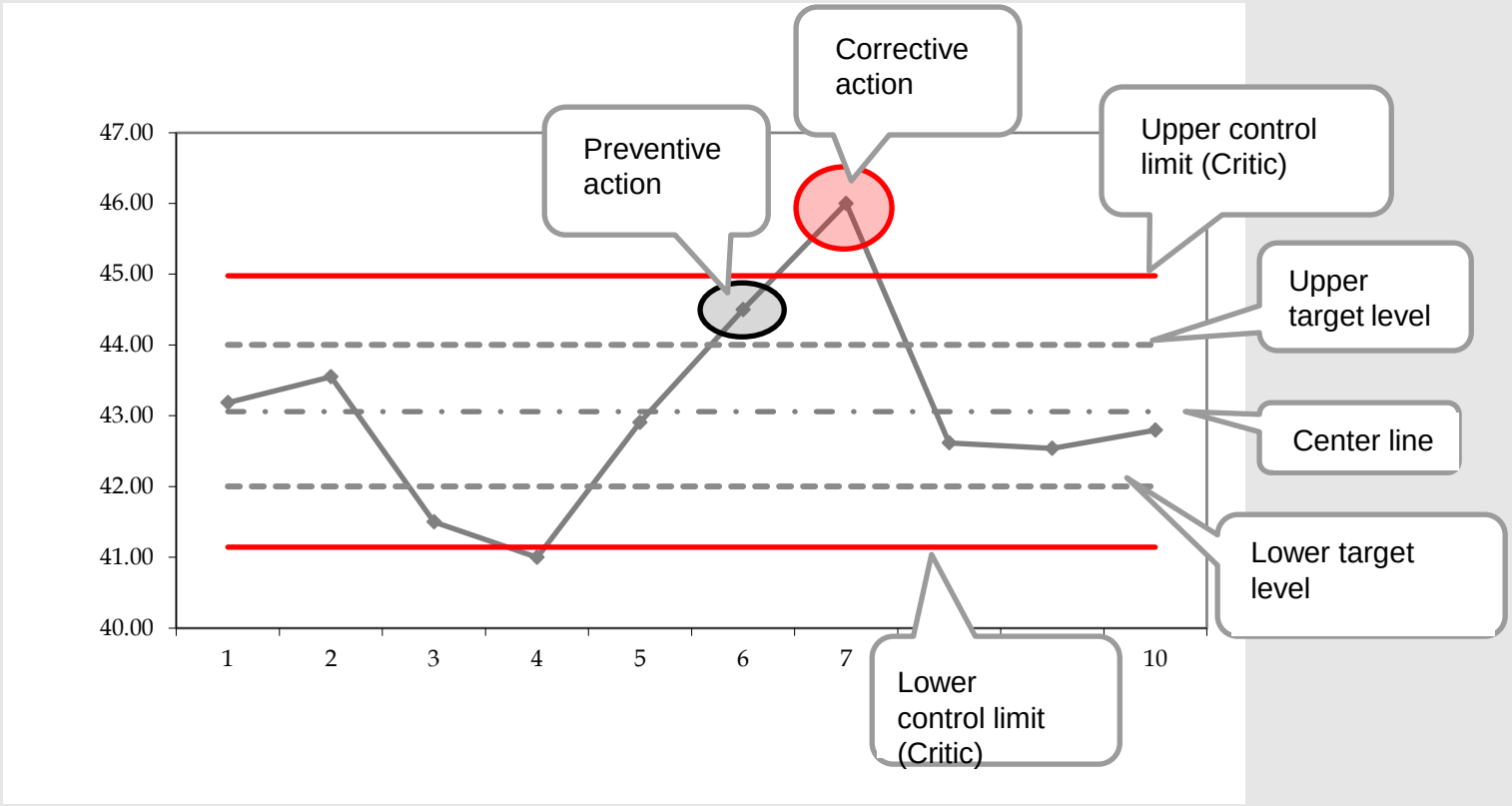


Variable control charts

	UCL & LCL	Mean	n*	A_2	D_3	D_4
X-Chart	$UCL_{\bar{x}} = \bar{\bar{x}} + A_2\bar{R}$ $LCL_{\bar{x}} = \bar{\bar{x}} - A_2\bar{R}$	$\bar{\bar{x}} = \frac{\sum_{i=1}^{n} \bar{x}_i}{n}$	2	1.88	0	3.27
			3	1.02	0	2.57
			4	0.73	0	2.28
			5	0.58	0	2.11
			6	0.48	0	2.00
R-Chart	$UCL_R = D_4\bar{R}$ $LCL_R = D_3\bar{R}$	$\bar{R} = \frac{\sum_{i=1}^{n} R_i}{n}$	7	0.42	0.08	1.92
			8	0.37	0.14	1.86
			9	0.34	0.18	1.82
			10	0.31	0.22	1.78

* Number of observations in each sample, UCL: upper control limit, LCL: lower control limit, A_2, D_3, and D_4 are constants


Upper control limit
Target
Lower control limit
Normal behavior
One plot out above (or below).
Investigate for cause.
Trends in either direction, 5 plots. Investigate for cause of progressive change.
Upper control limit
Target
Lower control limit
Two plots near lower (or upper) control.
Investigate for cause.
Run of 5 above (or below) central line.
Investigate for cause.
Erratic behavior.
Investigate.


Corrective action
Preventive action
Upper control limit (Critic)
Upper target level
Center line
Lower target level
Lower control limit (Critic)
47.00
46.00
45.00
44.00
43.00
42.00
41.00
40.00
1
2
3
4
5
6
7
10

Process control charts

Attribute control charts

Attribute charting is used for various types of defects, primarily by counting the number of nonconforming units or the nonconformities per units. The most commonly used attribute control chart is p-chart or the percentage of defective unit with variable sample size. The npchart is used to monitor the percentage defective unit for constant sample size. The c-chart is used to monitor the number of defects on an item for constant sample size. The u-chart is for number of unlimited defects in variable sample size.

	Defects	Defectives
Variable Sample Size	U - CHART	P – CHART
Constant Sample Size	C - CHART	NP - CHART

Chart	UCL and LCL	Center line
p	$UCL \alpha LCL = \bar{p} \pm 3\frac{\sqrt{\bar{p}(1-\bar{p})}}{\sqrt{n}}$	$\bar{p} = \frac{\sum np}{\sum n}$
np	$UCL \alpha LCL = n\bar{p} \pm 3\sqrt{n\bar{p}(1-\bar{p})}$	$n\bar{p} = \frac{\sum np}{k}$
c	$UCL \alpha LCL = \bar{c} \pm 3\sqrt{\bar{c}}$	$\bar{c} = \frac{\sum c}{k}$
u	$UCL \alpha LCL = \bar{u} \pm 3\frac{\sqrt{\bar{u}}}{\sqrt{n}}$	$\bar{u} = \frac{\sum c}{\sum n}$

n: the number of observations in each sample, k: number of samples

Control Chart Types

- Attributes
  - A quality characteristic measured by number of defects.
  - *p* and *np* charts
  - *c* and *u* charts
- Variables
  - A quality characteristic such as weight, length, time, temperature, voltage, etc.
  - *X*-bar and *R* charts
  - Chart for individual measurements.

Development of *p* Chart

- In statistical quality control, the p-chart is a type of control chart used to monitor the **proportion of nonconforming units in a sample**, where the sample proportion nonconforming is defined as the ratio of the number of nonconforming units to the sample size,
- Select at least 20 samples of size n (where $np \geq 3$).
- Calculate trial centerline

$$\bar{p} = \frac{\text{Total number of defectives}}{\text{Total number inspected}}$$

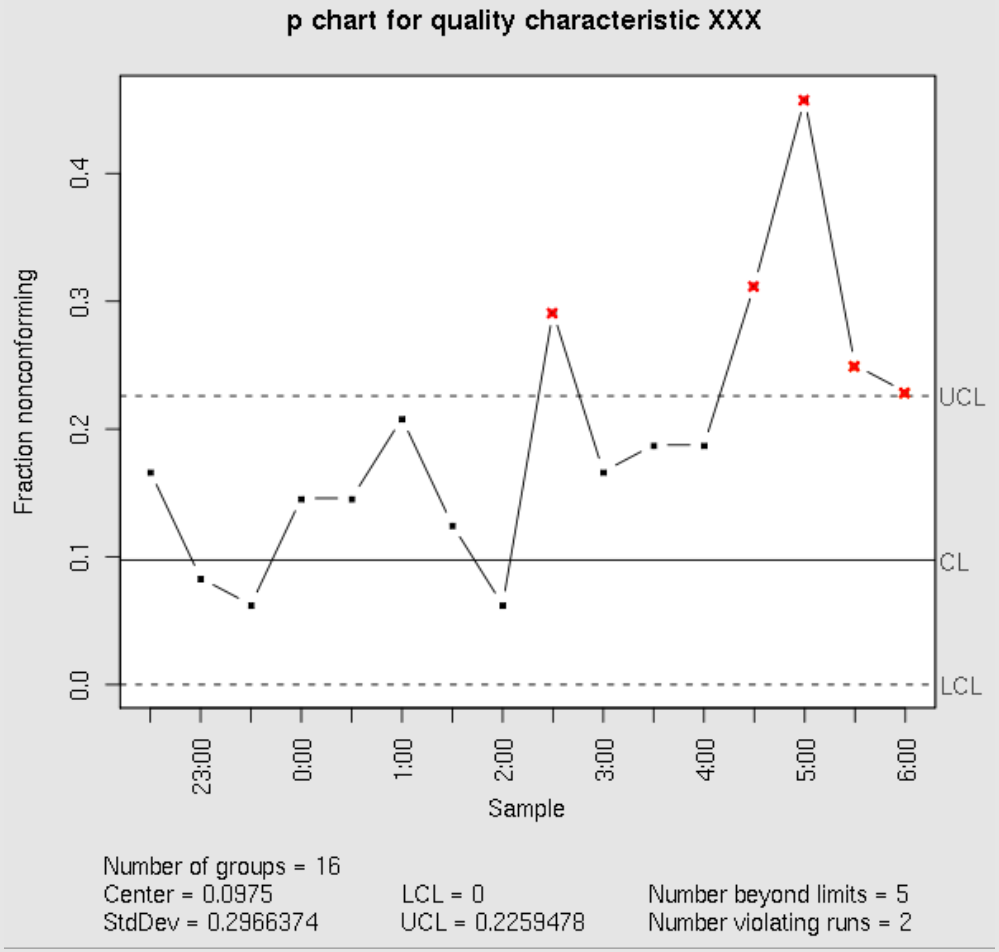
Run	Units Produced (Subgroup Size)	Number of DEFECTIVE units	Proportion Defective	UCL	LCL
1	42	5	0.1190	0.2699	0.0000
2	87	9	0.1034	0.2241	0.0153
3	53	6	0.1132	0.2534	0.0000
4	70	10	0.1429	0.2360	0.0033
5	101	13	0.1287	0.2165	0.0228
6	91	13	0.1429	0.2217	0.0176
7	36	4	0.1111	0.2819	0.0000
8	83	11	0.1325	0.2265	0.0128
9	64	7	0.1094	0.2414	0.0000

Development of *p* Chart

- Calculate trial control limits

$$UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$$

$$LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}}$$



Calculations for an *np* Chart

In statistical quality control, the np-chart is a type of control chart used to monitor the **number of nonconforming units in a sample**. It is an adaptation of the p-chart and used in situations where personnel find it easier to interpret process performance in terms of concrete numbers of units rather than the somewhat more abstract proportion.

The np-chart differs from the p-chart in only the three following aspects:

- The control limits are , where n is the sample size and is the estimate of the long-term process mean established during control-chart setup.
- The number nonconforming (np), rather than the fraction nonconforming (p), is plotted against the control limits.
- The sample size, , is constant.

$$Centerline = n\bar{p}$$

$$UCL = n\bar{p} + 3\sqrt{n\bar{p}(1-\bar{p})}$$

$$LCL = n\bar{p} - 3\sqrt{n\bar{p}(1-\bar{p})}$$

Run	Units Produced (Subgroup Size = constant)	Number of DEFECTIVE units	Proportion Defective
1	42	10	0.238
2	42	9	0.214
3	42	10	0.238
4	42	14	0.333
5	42	4	0.095
6	42	11	0.262
7	42	9	0.214

Center line

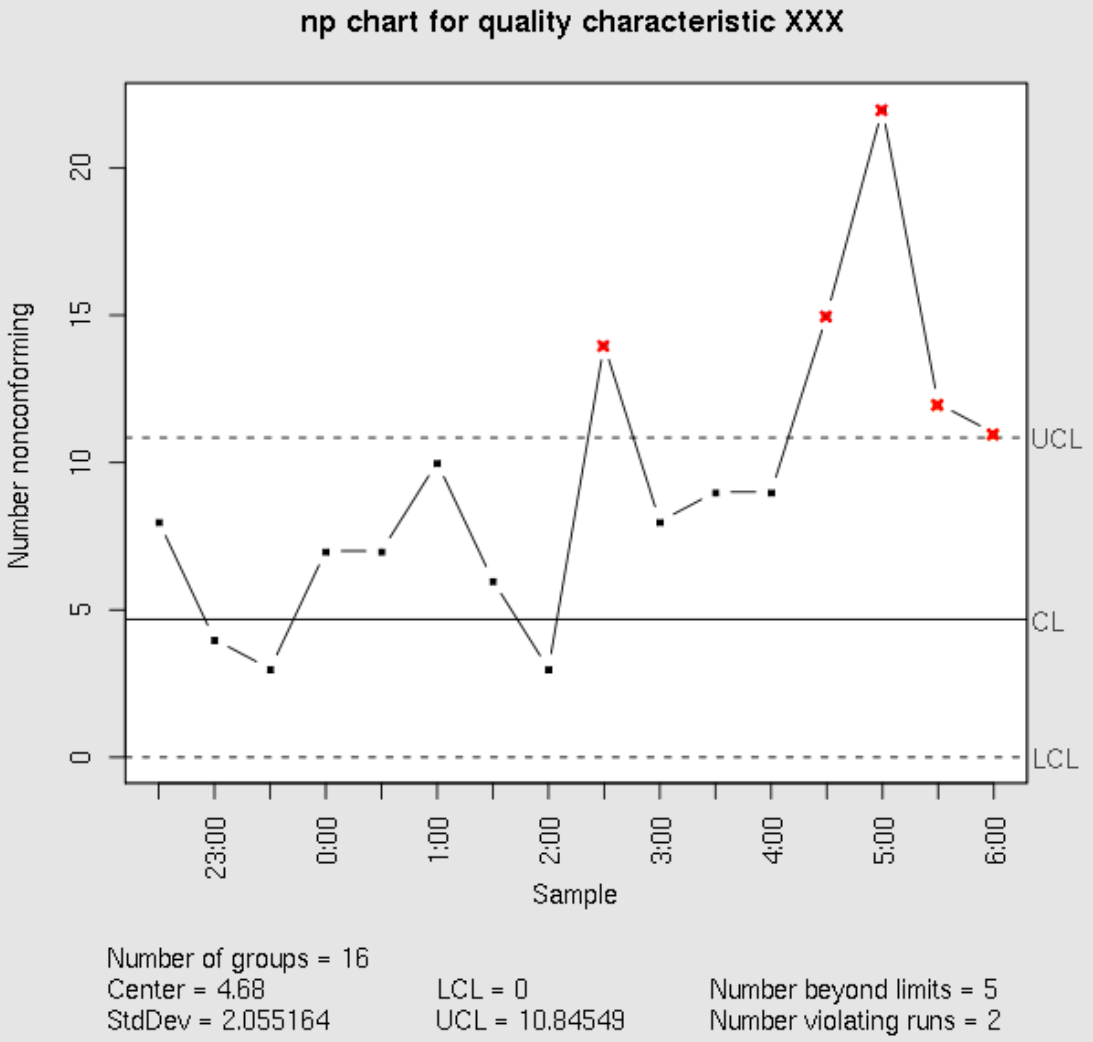
$$n\bar{p} = \frac{\sum_{i=1}^{m}\sum_{j=1}^{n}\begin{cases}1 & \text{if } x_{ij} \text{ defective}\\ 0 & \text{otherwise}\end{cases}}{m}$$

Control limits

$$n\bar{p} \pm 3\sqrt{n\bar{p}(1-\bar{p})}$$

Plotted statistic

$$n\bar{p}_i = \sum_{j=1}^{n}\begin{cases}1 & \text{if } x_{ij} \text{ defective}\\ 0 & \text{otherwise}\end{cases}$$



c Chart Calculations

In statistical quality control, the c-chart is a type of control chart used to monitor "count"-type data, typically total number of nonconformities per unit.[1] It is also occasionally used to monitor the total number of events occurring in a given unit of time.

The c-chart differs from the p-chart in that it accounts for the possibility of more than one nonconformity per inspection unit, and that (unlike the p-chart and u-chart) it requires a fixed sample size. The p-chart models "pass"/"fail"-type inspection only, while the c-chart (and u-chart) give the ability to distinguish between (for example) 2 items which fail inspection because of one fault each and the same two items failing inspection with 5 faults each; in the former case, the p-chart will show two non-conformant items, while the c-chart will show 10 faults.

$$\bar{c} = \frac{\text{Total number of defects in all items}}{\text{Total number of items}}$$

$$UCL = \bar{c} + 3\sqrt{\bar{c}}$$

$$LCL = Max\left\{\bar{c} - 3\sqrt{\bar{c}}, 0\right\}$$

Run	Units Produced (Subgroup Size = constant)	Number of DEFECTS	Defect/Unit (DPU)
1	12	10	0.833
2	12	9	0.750
3	12	10	0.833
4	12	14	1.167
5	12	7	0.583

u Chart Calculations

In statistical quality control, the u-chart is a type of control chart used to monitor "count"-type data where the sample size is greater than one, typically the average **number of nonconformities per unit**.

The u-chart differs from the c-chart in that it accounts for the possibility that the number or size of inspection units for which nonconformities are to be counted may vary. Larger samples may be an economic necessity or may be necessary to increase the area of opportunity in order to track very low nonconformity levels.

$$\bar{u} = \frac{\text{Total number of defects observed}}{\text{Total area inspected}}$$

$$UCL_i = \bar{u} + 3\sqrt{\bar{u}/a_i}$$

$$LCL_i = Max\left\{\bar{u} - 3\sqrt{\bar{u}/a_i}, 0\right\}$$

Run	Units Produced (Subgroup Size)	Number of DEFECTS	Defect/Unit (DPU)	UCL	LCL
1	42	10	0.238	0.6951	0.1083
2	87	32	0.368	0.6055	0.1978
3	53	10	0.189	0.6629	0.1405
4	70	14	0.200	0.6289	0.1744
5	101	37	0.366	0.5909	0.2125

TUTORIAL-1

The amount of moisture in the production of sucuk is one of the quality parameters. Moisture content should be around 40%. The X-bar (x) and R-chart graphics are created from the moisture contents of 5 samples of 10 runs.

n	Final moisture content for each run (kg water/100 kg total sucuk)									
	1	2	3	4	5	6	7	8	9	10
1	43,36	43,54	42,38	41,17	40,15	43,25	41,15	40,97	40,75	39,98
2	42,45	44,05	43,56	43,78	42,38	42,97	43,54	41,43	43,35	42,75
3	43,38	42,48	42,15	43,56	43,75	44,06	41,91	44,38	44,09	44,75
4	42,96	43,54	43,75	44,17	44,51	43,65	42,54	43,76	42,75	43,75
5	43,78	44,15	42,96	41,24	43,75	43,54	43,89	42,54	41,76	42,75

	UCL & LCL	Mean	n*	A_2	D_3	D_4
X-Chart	$UCL_{\bar{x}} = \bar{\bar{x}} + A_2\bar{R}$ $LCL_{\bar{x}} = \bar{\bar{x}} - A_2\bar{R}$	$\bar{\bar{x}} = \frac{\sum_{i=1}^{n} \bar{x}_i}{n}$	2	1.88	0	3.27
			3	1.02	0	2.57
			4	0.73	0	2.28
			5	0.58	0	2.11
			6	0.48	0	2.00
R-Chart	$UCL_R = D_4\bar{R}$ $LCL_R = D_3\bar{R}$	$\bar{R} = \frac{\sum_{i=1}^{n} R_i}{n}$	7	0.42	0.08	1.92
			8	0.37	0.14	1.86
			9	0.34	0.18	1.82
			10	0.31	0.22	1.78

* Number of observations in each sample, UCL: upper control limit, LCL: lower control limit, A_2, D_3, and D_4 are constants

n	Final moisture content for each run (kg water/100 kg total sucuk)									
	1	2	3	4	5	6	7	8	9	10
1	43,36	43,54	42,38	41,17	40,15	43,25	41,15	40,97	40,75	39,98
2	42,45	44,05	43,56	43,78	42,38	42,97	43,54	41,43	43,35	42,75
3	43,38	42,48	42,15	43,56	43,75	44,06	41,91	44,38	44,09	44,75
4	42,96	43,54	43,75	44,17	44,51	43,65	42,54	43,76	42,75	43,75
5	43,78	44,15	42,96	41,24	43,75	43,54	43,89	42,54	41,76	42,75
$\overline{X}$	43,19	43,55	42,96	42,78	42,91	43,49	42,61	42,62	42,54	42,80
UCL- $\overline{X}$ =44,52										
LCL- $\overline{X}$ =41,37										
$\overline{\overline{X}}$ =42,94										
R	1,33	1,67	1,6	3	4,36	1,09	2,74	3,41	3,34	4,77
UCL- $\overline{R}$ =5,77										
LCL- $\overline{R}$ =0										
$\overline{R}$ =2,73