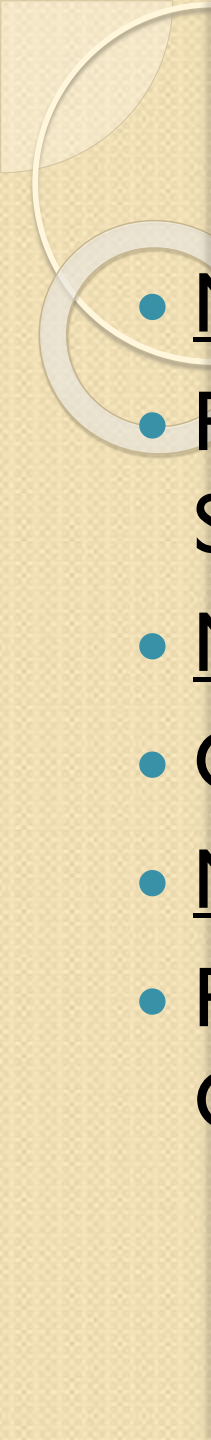




THE MANAGEMENT AND CONTROL OF PRODUCT QUALITY

Taiwo Oteju

- 
- Module 1
 - Product, Product Quality and Management Systems
 - Module 2
 - Quality Improvement Tools and Standards
 - Module 3
 - Regulatory Framework and the role of Chemists/Public Analysts



Module I

Product Quality and Management Systems

What Is A Product

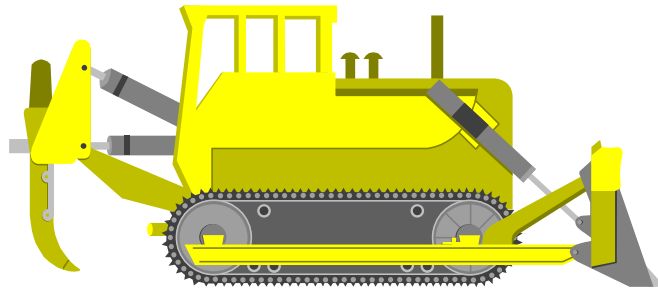
- Anything that satisfies consumer needs
- Anything a consumer acquires to meet a perceived need
- Anything that can be offered to a market for attention, acquisition, use or consumption to satisfy a human need or want
- Product or market offering consist of:
 - Tangible objects
 - Services
 - Other components (ideas, events, information, places, experiences etc.)

What is Quality

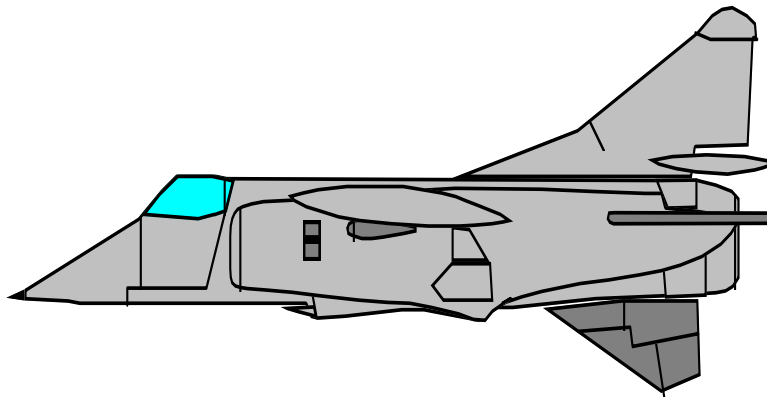
- British Standard – Fitness for purpose
- Crosby – Conformance to requirements
- Juran – Fitness for use
- Deming – a predictable degree of uniformity and dependability at a low cost suited to the market
- ISO – the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs

“Good Quality”

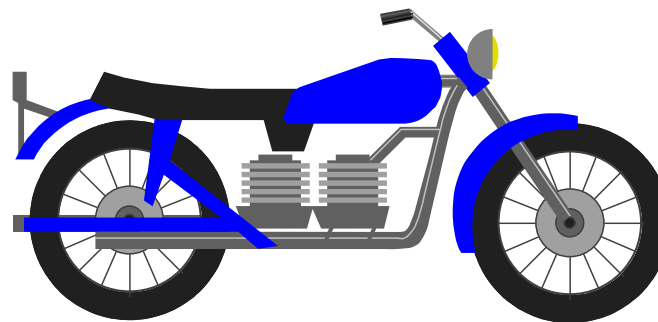
- What do we mean by “Good Quality”?
- Let’s think about some means of transportation



Bulldozer



Jet plane



Motor cycle

Which is the “Better Quality vehicle?”



Required purpose

1/ To travel to London

2/ To move a pile of bricks

3/ To deliver a parcel in Lagos

Which vehicle is best suited to each duty?

Quality = a consistently reliable standard which is “Fit for purpose”

- All the “Vehicles” we have looked at could be examples of “**Good Quality**”, if they do what we want them to do, consistently and reliably.
- They might be of “**Poor quality**” if they break down, or don’t do the job we want them to do, (or are too expensive compared with competitive vehicles.)
- *Quality isn’t about luxury, it’s about consistently giving the customer what he expects.*
- Good Quality means giving customers what they want, on time, every time, at the right cost.

Quality Control

- Quality Control is a quality system which is concerned with sampling, specifications testing, organization, documentation and release procedures which ensure that the necessary test are carried out and that materials are not released for use, nor products for sale or supply until their quality has been adjudged to be satisfactory. (ISO)
- It is a system of routine technical activities, to measure and control the quality of product as it is being produced.

Quality Control

Mainly Testing & Inspection

Tests :

- quality of samples of material from Suppliers.
- Quality of in-process samples
- quality of our finished goods

The level of Q.C. must be enough to :

Give us confidence that we are:

- **receiving** materials that meet **specification**,
- **producing** satisfactory products.

Quality Assurance

- Quality Assurance is the sum total of the organized arrangements made with the objective of ensuring that products will be of the quality required by their intended use. It involves the original product design and development as well as defined processes which when followed will yield a product that complies with the specifications in quality, safety, purity efficacy and wholesomeness. (ISO)
- The totality of planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy customer's requirements.

Quality Assurance

Systems, Validation, Audits.

Aims to ensure that :

- Processes and procedures are always followed which have been proved to produce good product every time.
- Quality materials are used from qualified and trusted suppliers.
- Validated methods are used.

Quality Control and Quality Assurance

- Quality control functions to test and measure materials and products while Quality Assurance establishes systems for ensuring the Quality of products.
- QC is about detection and corrective action while QA is about preventive action.



Quality Management.

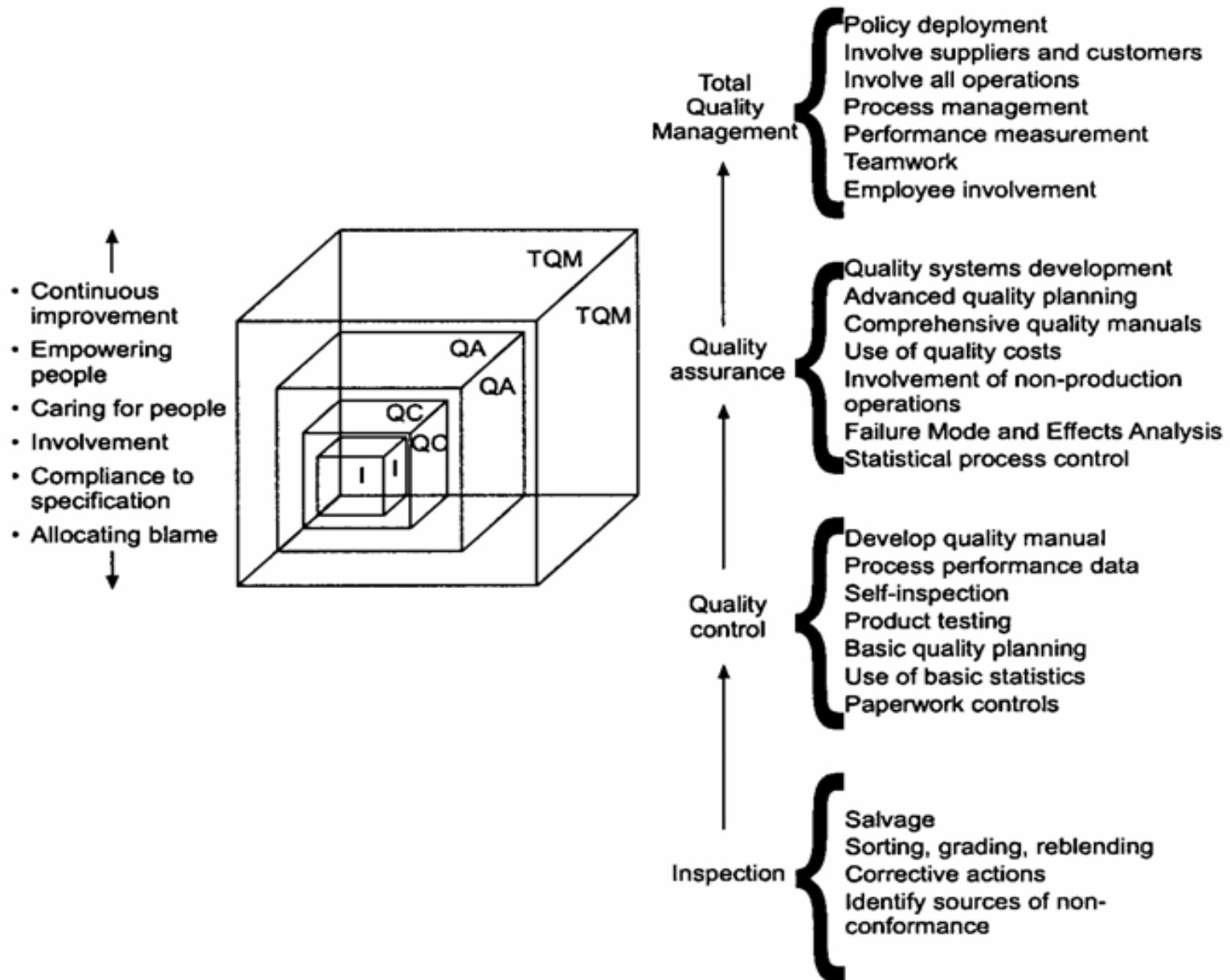
A Quality Management System
will be used to ensure good quality
in products

The System will combine
Quality Control
with
Quality Assurance

The right balance.

- The most reliable and cost-effective Quality Systems will combine a lot of Quality Assurance with a small amount of Quality Control.
- Quality Control on its own is expensive, and unreliable.
- Quality Assurance on its own places too much trust in suppliers and systems.
- ***Combine the right amounts of QA & QC and you will get a good system!***

The four levels in the evolution of Quality Management



There are a number of Quality improvement Gurus who are the pioneers in the introduction of concepts, principles, tools and techniques that served as the foundation of modern quality improvement.

Feigenbaum

Total Quality Control - an organisational approach which matured through Japanese adoption into TQM.



Shewhart

Shewhart is considered the father of statistical process control and understanding variation.



Deming

He is considered as the father of the quality improvement movement & accredited with:

PDCA Cycle 14 Points to quality



Taguchi

He drove the use of statistical process control techniques through design and is known for his Quality Loss Function and Off-line Quality Control



Juran

One of the first to write about the cost of poor quality, Juran developed an approach for cross-functional management that comprises three legislative processes Quality Planning, Control and Improvement



Crosby

He developed the philosophy of Zero Defects and Doing it Right First Time



Quality Gurus



Module 2

Quality Management Tools and Standards

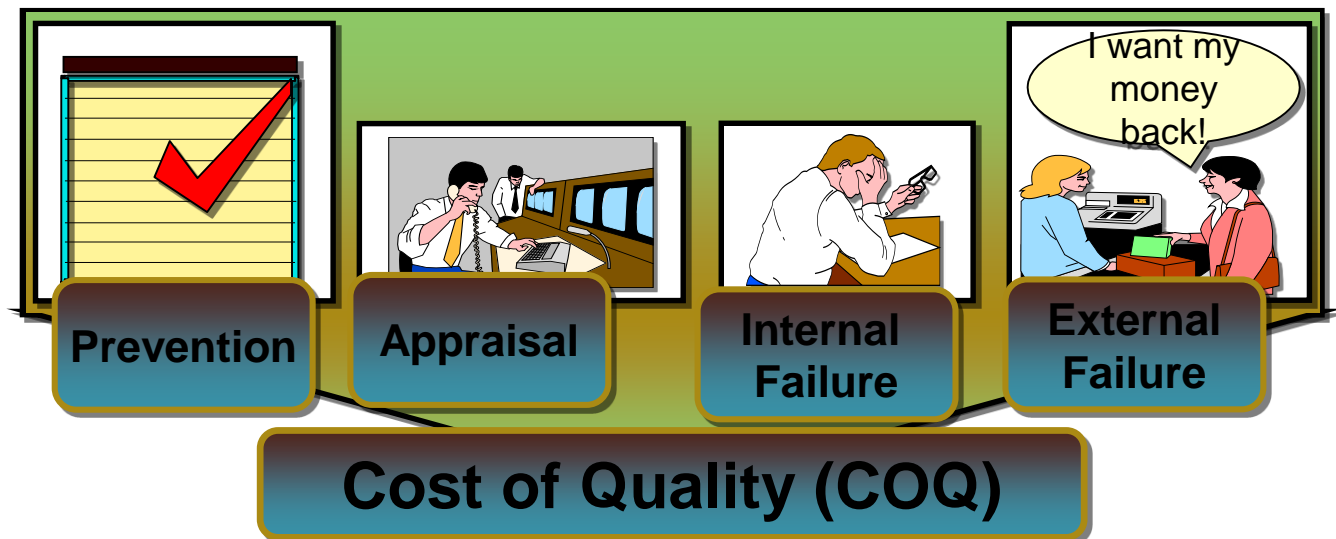


Quality Management Tools and Standards

- Cost of Poor Quality
- 5S Technique
- Good Manufacturing Practices
- Good Storage/Distribution Practices
- ISO 9001:2015
- HACCP
- Kaizen
- Lean and Six Sigma

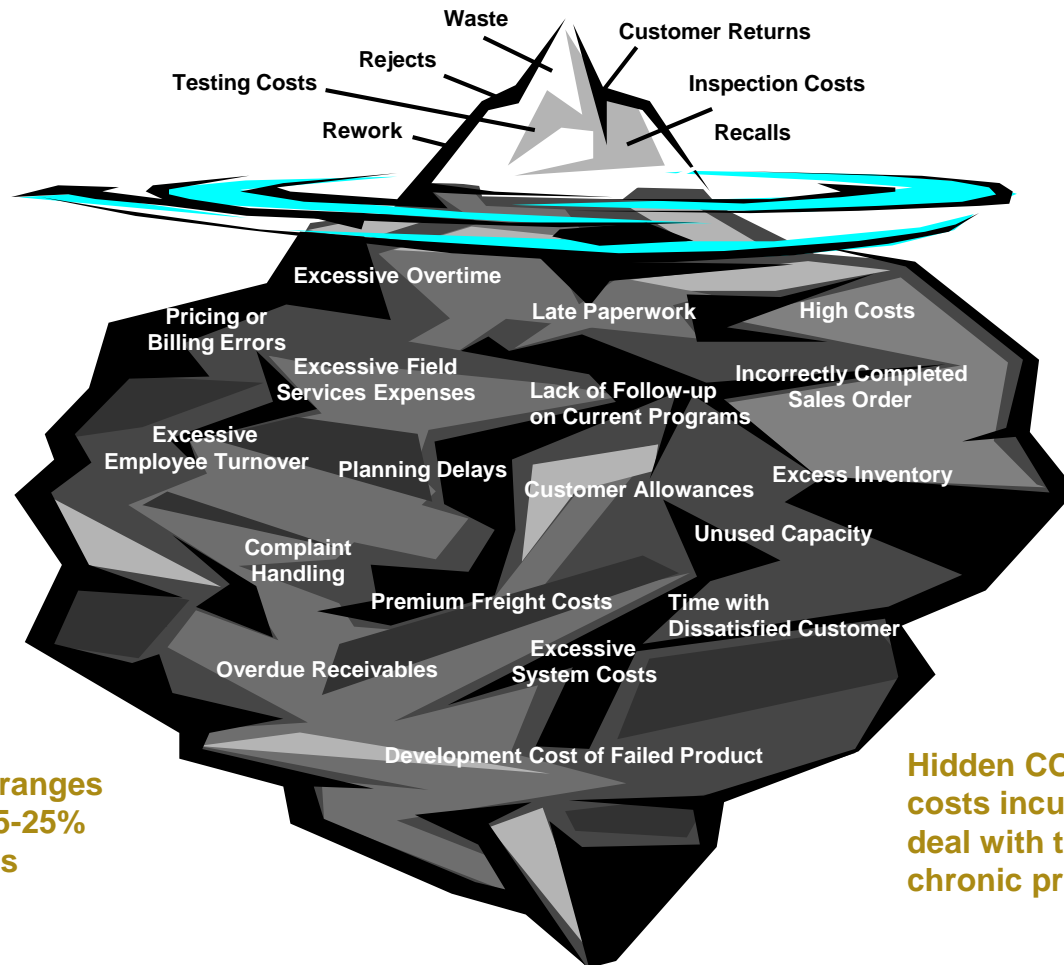
Costs of Quality

- **Appraisal.** Any activity concerned with checking that requirements have been carried out and that product or process is acceptable e.g. testing, product/material audit, process control measurements etc **Quality Control.**
- **Prevention.** Activities aimed at preventing defects e.g. documentation, training, planning, market research, etc. **Quality Assurance.**
- **Failure.** Any cost resulting from not getting things right first time e.g. scrap, rework, rejects complaints, returns, etc. **Waste!**



Cost of Poor Quality

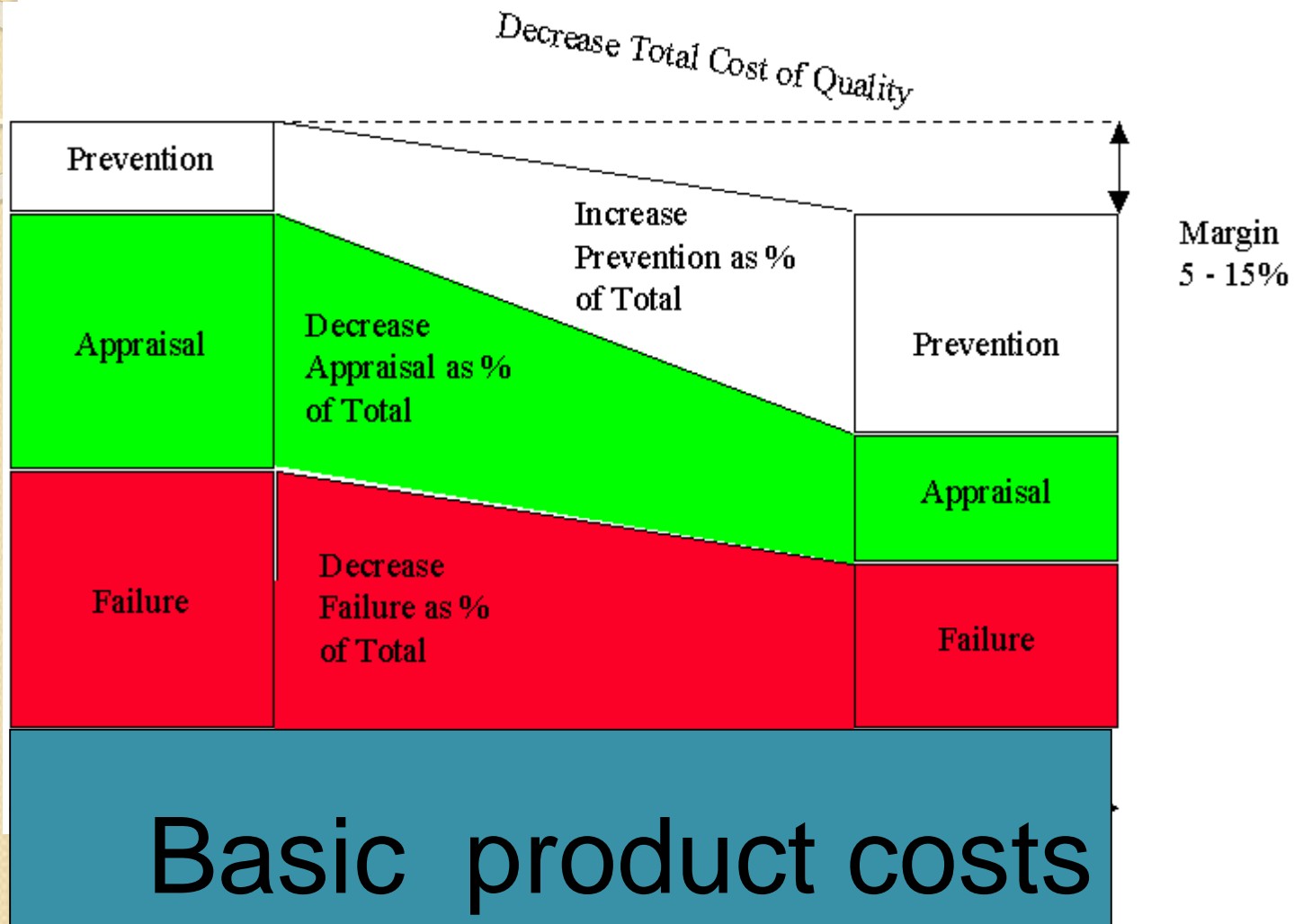
As an organization gains a broader definition of poor quality, the hidden portion of the iceberg becomes apparent.



COPQ ranges from 15-25% of Sales

Hidden COPQ: The costs incurred to deal with these chronic problems

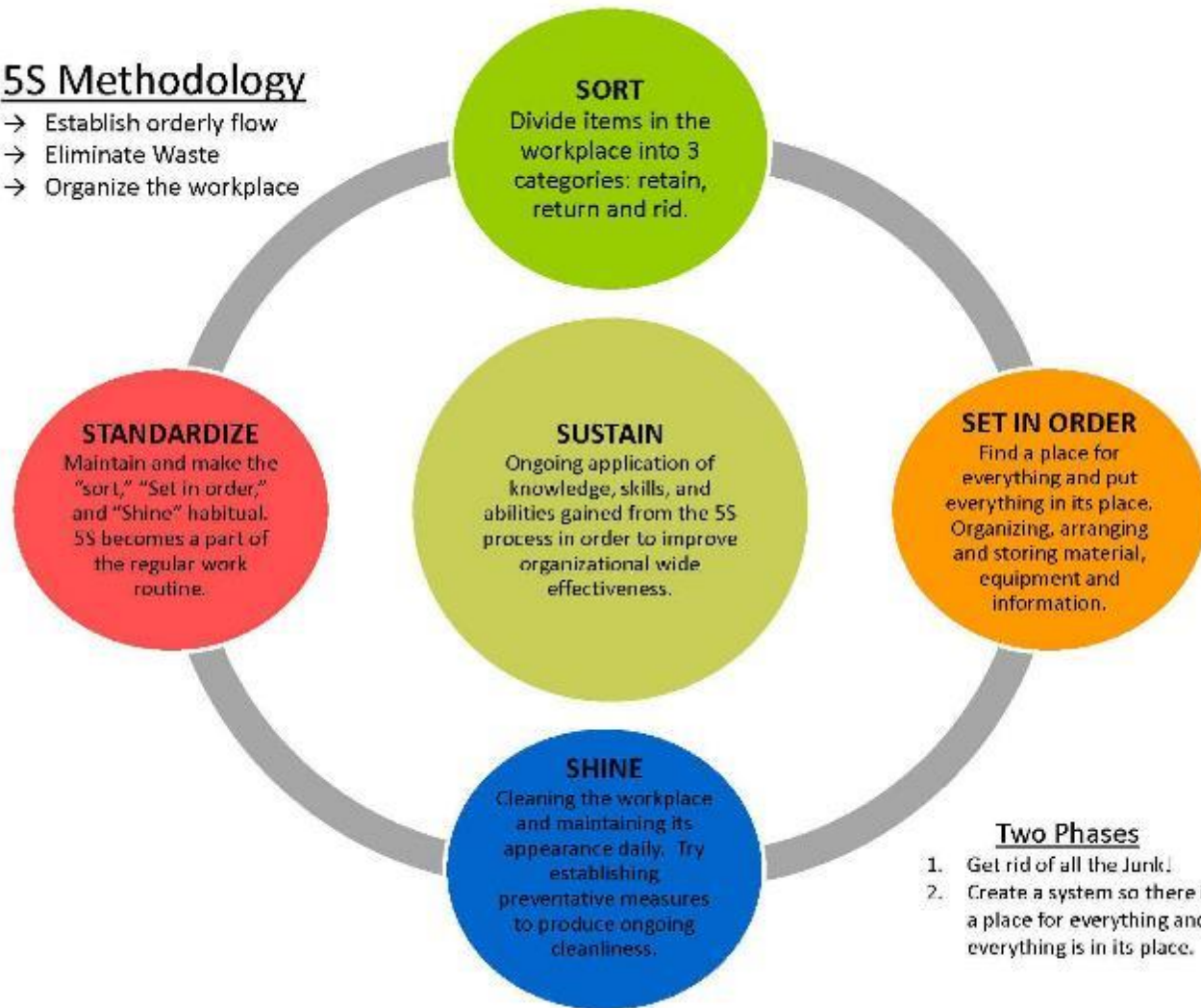
Minimising Quality Costs: Effect of QMS



5S Methodology

5S Methodology

- Establish orderly flow
- Eliminate Waste
- Organize the workplace



Good Manufacturing Practices (GMP)

- GMP's are regulations that prescribe the methods, equipment, facilities and controls required for manufacturing and packaging of products
- It is that part of Quality Assurance which is aimed at ensuring that products are **consistently** manufactured and controlled to a quality standards **appropriate** to their intended use and as required by product specification

Components of GMP



Good Storage/Distribution Practices



- Standards for GDP
 - WHO GDP
 - EU GDP
- Components
 - Documentation
 - Quality Systems
 - Recalls/Returns
 - Premises and Equipment
 - Access & Warehouse Controls
 - Transportation
 - Personnel
 - Self Inspection
 - Dispatch and Receipt

ISO



International
Organization for
Standardization

- International Organisation for Standardization (ISO) started formal operations on February 23 1947
- Objective: To facilitate the international coordination and unification of industrial standards
- ISO is a network of the national standards institutes of 162 countries, on the basis of one member per country, with a central secretariat in Geneva Switzerland
- ISO has developed more than 21884 standards since inception through its 3000 technical committees, subcommittees and working groups



Hallmarks of the ISO System

- Equal footing
- Voluntary
- Market Driven
- Consensus
- Worldwide membership and application of standards

How ISO Standards benefit society

- ***For businesses***, the widespread adoption of International Standards means that suppliers can base the development of their products and services on specifications that have wide acceptance in their sectors
- ***For customers***, the worldwide compatibility of technology which is achieved when products and services are based on International Standards brings them an increasingly wide choice of offers, and they also benefit from the effects of competition among suppliers.
- ***For governments***, International Standards provide the technological and scientific bases underpinning health, safety and environmental legislation.
- ***For trade officials*** The existence of divergent national or regional standards can create technical barriers to trade. International Standards are the technical means by which political trade agreements can be put into practice.

How ISO Standards benefit society

- ***For developing countries***, By defining the characteristics that products and services will be expected to meet on export markets, International Standards give developing countries a basis for making the right decisions when investing their scarce resources and thus avoid squandering them.
- ***For consumers***, conformity of products and services to International Standards provides assurance about their quality, safety and reliability.
- ***For everyone***, International Standards can contribute to the quality of life in general by ensuring that the transport, machinery and tools we use are safe.
- ***For the planet*** we inhabit, International Standards on air, water and soil quality, and on emissions of gases and radiation, can contribute to efforts to preserve the environment.

1987

➤ 5 Series of Standards:

ISO 9000 Guide to selection and use
ISO 9001

Specification for design/development, production, installation and servicing
ISO 9002

Specification for production installation
ISO 9003

Specification for final inspection and test
ISO 9004 Guide to quality management and quality system elements

1994

• 3 Series of Standards:

- ISO 9001:1994

- ISO 9002:1994

- ISO 9003:1994

2000

ISO 9000 Series of Standards:

- ISO 9000:2000 Fundamentals and Vocabulary

- ISO 9001:2000 Quality Management Systems - Requirements

- ISO 9004:2000 Guidance for Performance Improvement

2008

ISO 9000 Series of Standards:

- ISO 9000:2008 Fundamentals and Vocabulary

- ISO 9001:2008 Quality Management Systems - Requirements

- ISO 9004:2008 Guidance for Performance Improvement

2015

Related Standards

- ISO 13485:2003 Medical Device Quality Systems
- ISO 14001: Environmental Management Systems
- ISO 14001:2004 EMS Specifications with Guidance for Use
- ISO 14004:2004 EMS General Guidelines on Principles, Systems and Supporting Techniques
- OHSAS 18001:1999 Occupational Health & Safety Management
- ISO 20000:2005 IT Service Management Standard
- ISO 17799:2005 Information Security Management Systems
- ISO 90003:2004 Software Quality Management Systems
- ISO 10001:2005 Guidance for codes of Conduct for organizations
- ISO 1002:2005 Quality Management – Customer satisfaction – Guidance to complaints handling in organisations
- ISO 1003:2005 Guidance for dispute Resolution external to organizations
- ISO 19011: Guidelines to Quality and/or environmental Systems auditing
- ISO 17025:2005 Laboratory Management Systems
- ISO/TC 16949:2002 Automotive quality standard
- ISO 10005:2005 QMS – Guidelines for Quality plans
- ISO 10006:2003 QMS Guidelines quality management project management
- ISO 10011:1990 Guideline for auditing quality systems
- ISO/IEC 17025 Competence Requirements for Testing and Calibration Laboratories

ISO 9001

- Is not a Law
 - Is not a Regulation
- It simply means:
- Say what you do
 - Do what you say
 - Check it and Act/Prove that you do it



ISO 9001 Quality Management Principles

1. CUSTOMER FOCUS

2. LEADERSHIP

3. INVOLVEMENT OF PEOPLE

4. PROCESS APPROACH

5. SYSTEM APPROACH

6. CONTINUAL IMPROVEMENT

7. FACTUAL APPROACH TO DECISION MAKING

8. MUTUALLY BENEFICIAL SUPPLIERS-CUSTOMER RELATIONSHIPS

Requirements of ISO9001:2015

1. Scope

2. Normative Reference

3. Terms and definitions

4. Context of The Organisation

- Understanding the organisation
- Understanding the needs and expectations of interested parties
- Determining the scope of the QMS
- Quality Management System and its processes

5. Leadership

- Leadership and Commitment
- Policy
- Organisational Roles, Responsibilities and Authorities

6. Planning

- Actions to address risks and opportunities
- Quality Objectives and Planning to achieve them
- Planning of Changes

7. Support

- Resources
- Competence
- Awareness
- Communication
- Documented Information

8. Operation

- Organizational Planning and Control
- Requirements for Products and Services
- Design and Development of products and services
- Control of externally provided products and services
- Production and Service Provision
- Release of products and services
- Control of non conforming products

9. Performance Evaluation

- Monitoring, Measurement Analysis and Evaluation
- Internal Audit
- Management Review

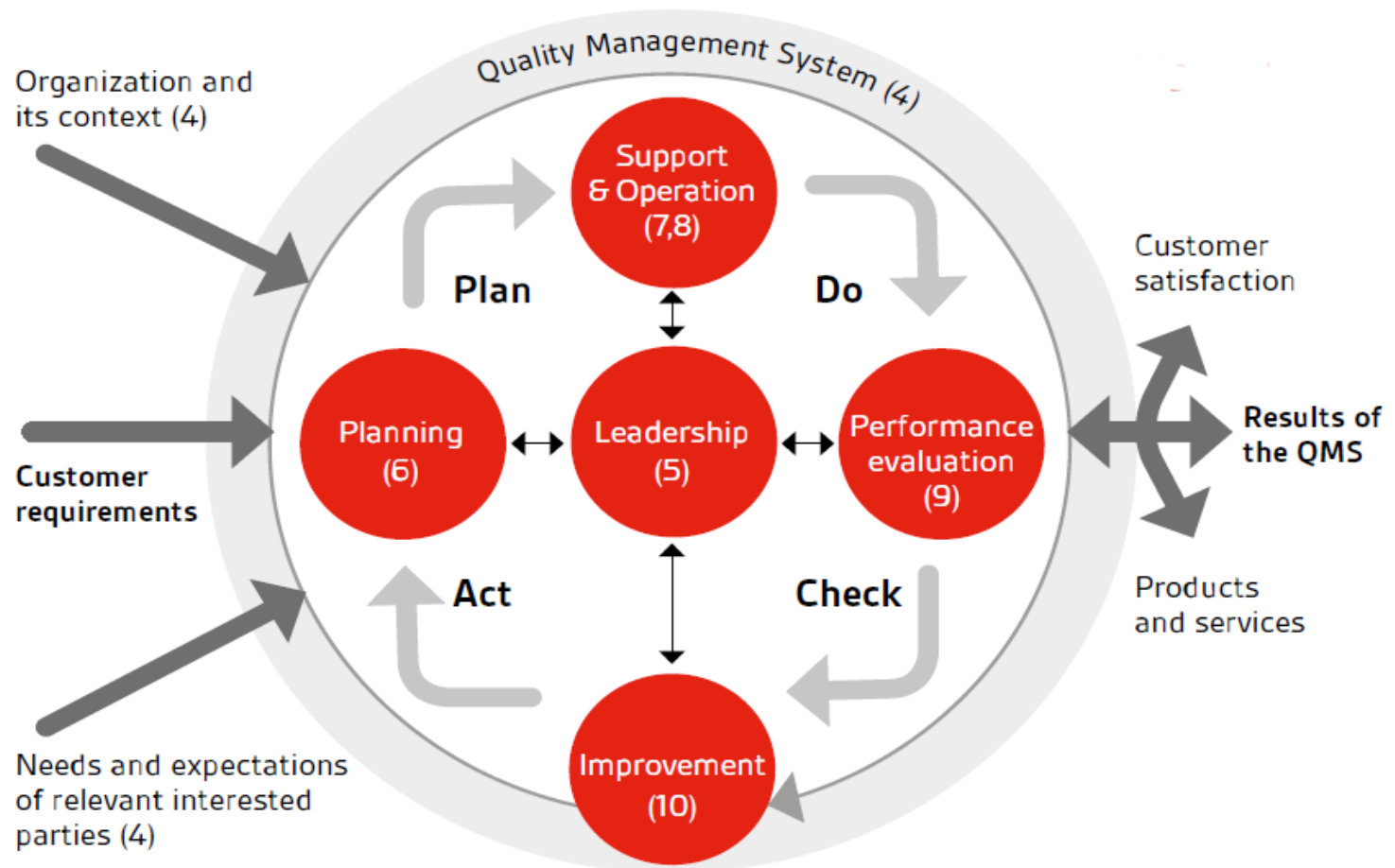
10. Improvement

- General
- Non Conformity and Corrective Action
- Measurement Analysis and Evaluation
- Internal Audit
- Management Review

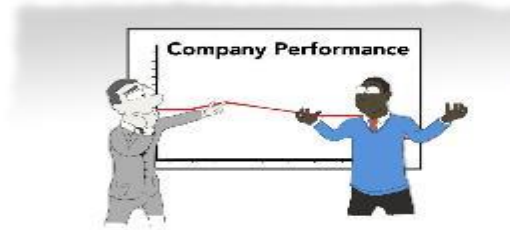
The Process Model

Any activity or operation which receives inputs and converts them to outputs is a process, which covers almost all product and/or service activities and operations. For organisations to function they have to define and manage numerous inter-linked processes.

The process model for ISO 9001 shows its four main elements following the Plan-Do-Check-Act cycle. It is simply a way of representing an organisation's quality management system in relation to customer's requirements and the achievement of customer satisfaction.



Why Have an ISO Standard?



- Improved consistency of service and product performance
- Higher customer satisfaction levels.
- Improved customer perception
- Improved productivity and efficiency
- Cost reductions
- Improved communications, morale and job satisfaction
- Competitive advantage and increased marketing and sales opportunities.

Hazards Analysis & Critical Control Point (HACCP)

What is HACCP?

- A Food Safety Programme which moves away from reliance upon 'end testing' of products & customer complaints to understand food safety
- HACCP allows manufacturers to identify hazards as they could occur through the stages of production so that adequate measures can be implemented so they can be prevented
- HACCP Team includes: Technical Managers, Company Engineers, Microbiologist, Quality Manager, Supervisors, External Specialists



7 Process Steps of HACCP

The HACCP system involves seven steps :

7. Establish a record system

A HACCP system should be supported by comprehensive, effective and accurate records for reference and review. They include records on food product safety, process steps, food storage; monitoring and corrective action etc.



6. Establish verification procedures

Establish verification procedures to ensure that the HACCP system is functioning properly.



5. Establish corrective actions

Establish corrective actions in advance for CCPs so as to correct deviations of the limits quickly and prevent unsafe products from entering into the market.



1. Analyse hazards

Analyse the whole food production process and identify hazards posed to the safety of food.



2. Determine critical control points (CCPs)

Determine critical control points at which hazards can be controlled or eliminated. Common CCPs in food production are in the following process steps: purchase of raw materials, cold storage of raw materials, cooking, cold- and hot-holding of prepared food.



3. Establish limits for CCPs

Establish a set of clear limits for CCPs for the food to comply with. These can be limits of cooking temperature, cooking time and physical properties, e.g. food colour, appearance, texture, etc.



4. Establish monitoring procedures for CCPs

The purpose of monitoring procedures is to assure that the food meets the limits set for CCPs, e.g. the temperature limit, or cooking or cooling time limit. Major monitoring procedures include visual inspections and physical measurements such as temperature readings. Besides, the frequency and time of the monitoring procedures should be specified.



KAIZEN

- A system of continuous improvement in quality, technology, processes, company culture, productivity, safety and leadership.
- Kaizen, a Japanese word means continuous improvement.



Kaizen Principles

Kaizen

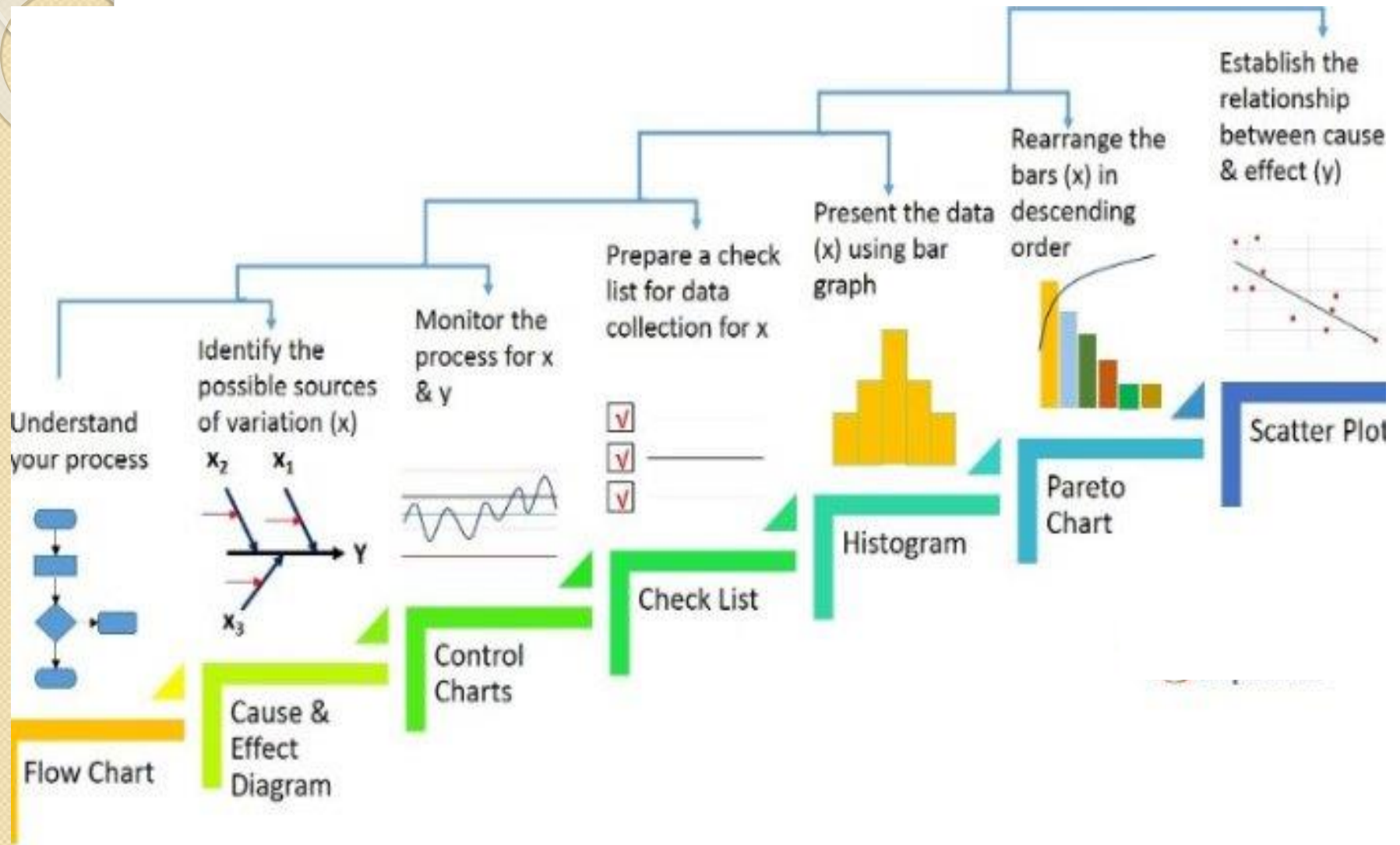
- ▶ Customer Orientation
- ▶ Total Quality Control/Six Sigma
- ▶ Robotics
- ▶ Quality Circles
- ▶ Suggested System
- ▶ Automations
- ▶ Discipline in the Workplace
- ▶ Total Productive Maintenance (TPM)
- ▶ Kanban
- ▶ Quality Improvement
- ▶ Just-In-Time (JIT)
- ▶ Zero Defects
- ▶ Small-Group Activities
- ▶ Cooperative Labor/Management Relations
- ▶ Productivity Improvement
- ▶ New Product Development



Kaizen Event Process



7 Quality Control Tools



Lean and Six Sigma

A POWERFUL UNION

LEAN

**SAFETY
DELIVERY
SPEED
QUALITY
LESS WASTE**

SIX SIGMA

**CONSISTENCY
ACCURACY
STABILITY
QUALITY**



**MEET CUSTOMER EXPECTATIONS
EMPLOYEE & PARTNERSHIP GROWTH
IMPROVED PROFITABILITY
EXPANDED CAPACITY
GREATER FLEXIBILITY**

Lean - Elimination of Wastes



D: Defects
O: Overprocessing
W: Waiting
N: Non Utilized Skill
T: Transportation
I: Inventory
M: Motion
E: Excess Production

....Eliminating Waste and becoming healthy, fit, agile and efficient.

History of Six Sigma

- ☐ The origin of Six Sigma as a measurement standard traces its history back to Carl Fredrick Gauss (1777-1885) who is credited with the introduction of “Normal Curve” concept.
- ☐ But the credit for coining the term “Six Sigma” goes to a Motorola engineer named ‘Bill Smith’.
- ☐ In the mid 1980’s, the Motorola engineers along with its’ chairman Bob Galvin thought that the traditional quality levels measured as ‘defects in thousands of opportunities’ did not provide much granularity. In effect, they wanted to measure ‘defects per million opportunities’.
- ☐ Therefore, Motorola undertook the initiative to develop this new standard and created the methodology and the associated cultural change required for implementing Six Sigma.
- ☐ After Six Sigma became a standard practice at Motorola, it was hugely admired by the many American Leaders such as Larry Bossidy of Allied Signal (presently Honeywell, adopted Six Sigma in 1993) and Jack Welch of General Electric (launched Six Sigma in 1995) etc.

Theory of Six Sigma

Sigma Performance Levels - One to Six Sigma

Sigma Level Defects Per Million Opportunities (DPMO)

1 690,000

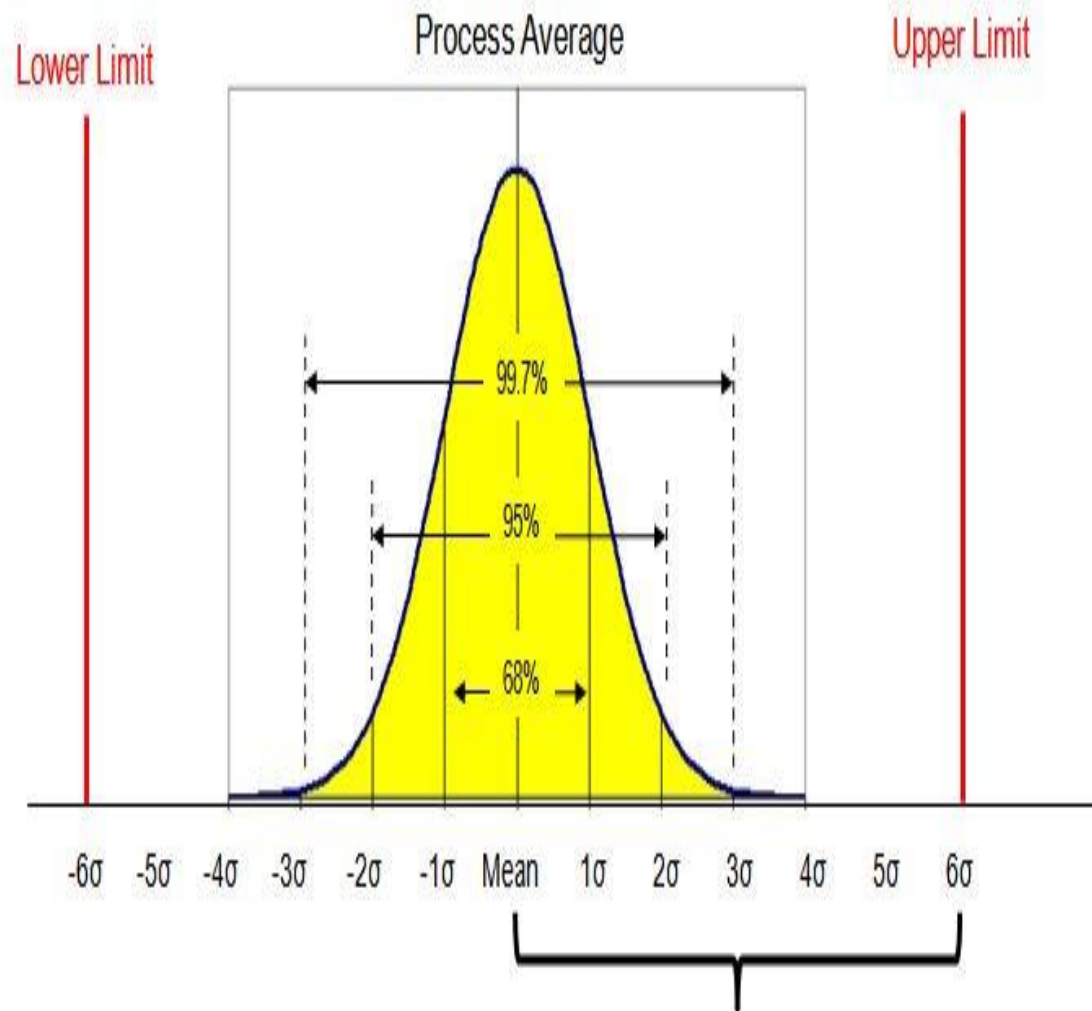
2 308,537

3 66,807

4 6,210

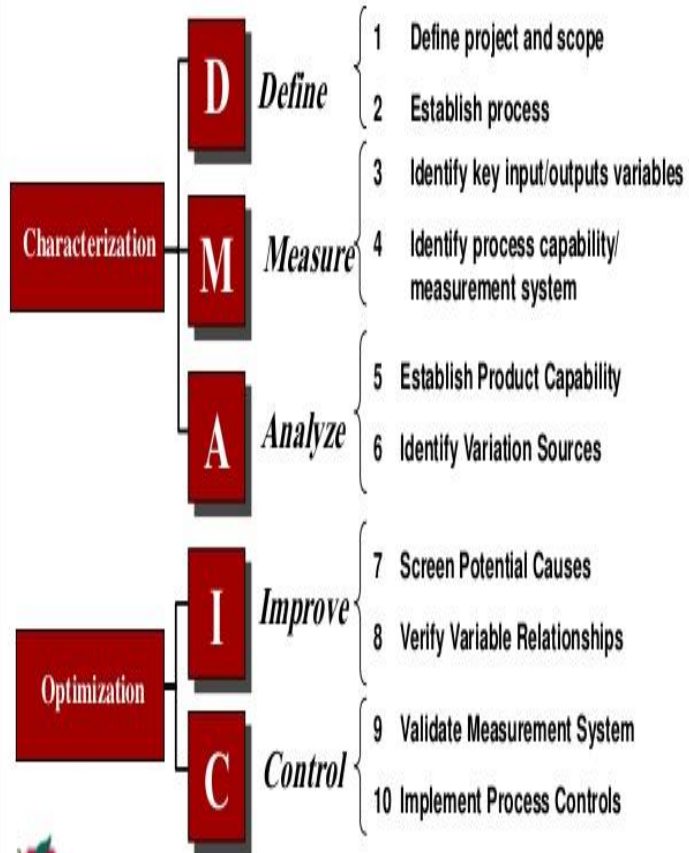
5 233

6 3.4



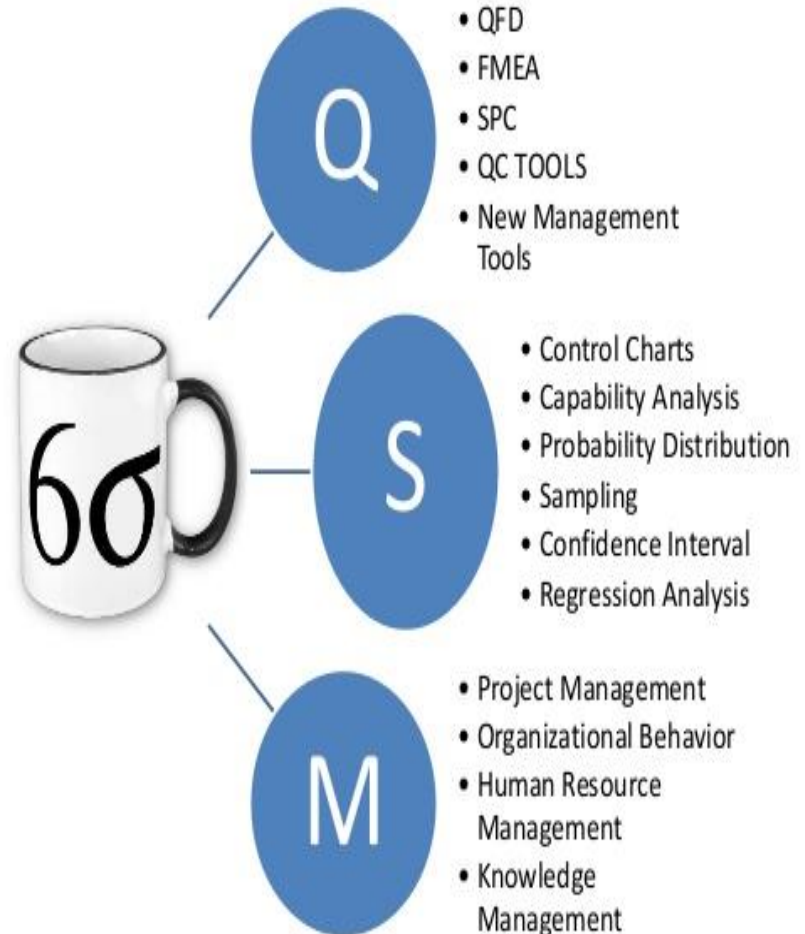
Analytical and Management Tools of 6 Sigma

The 6 Sigma Breakthrough Method



Sl. #17

SIX SIGMA TOOLS



Six Sigma companies



Living.
Improved daily.



Module 3

Regulatory Framework and The Role of Chemists



NAFDAC



SON

IPAN



NAFDAC



- Established by NAFDAC Act 15 of 1993
- NAFDAC's Mission
 - Established to regulate and control the importation, exportation, manufacture, distribution, sale and use of food, drugs, cosmetics, medical devices, detergents, packaged water and chemicals
 - Public Health Protection and promotion by ensuring that safe products are made available to the Nigerian public
 - NAFDAC also regulate product quality



NAFDAC's Role

- Educate Industry in Regulations
- Holding scientific workshops with stakeholders
- Leverage available expertise (within government, industry sector, academics)
- Be a knowledge base for industry (website, data bank, trade/research, association contacts)
- Technical support facilities



Sources of information in making regulations

- WHO
- FAO
- Codex Alimentarius Commission
- Pharmacopoeias
- Reference books
- Scholarly articles and Research publications
- Regulatory agencies of advanced countries

Regulatory Practices

- Import Permits for RM
 - Submission of MSDS, COA and technical documents
- Product Registration and NAFDAC Registration Numbers
 - Submission of Important Documents
 - Factory GMP Inspection
 - Third Party Analysis (Public Lab)
 - Product Analysis
- Embossment of Tablets/Capsules
- Inclusion of dispensing device in Liquid medicines
- Herba; medicines and related products
- Food fortification with useful ingredients

Standards Organisation of Nigeria

- The STANDARDS ORGANISATION OF NIGERIA (SON) is the apex standardization body in Nigeria.
- SON was established by SON Act No. 14, 2015, which repeals the Standards Organisation of Nigeria Act, Cap 59 laws of Federal Republic of Nigeria, 2004, and Enact the STANDARDS ORGANISATION OF NIGERIA Act. 2015 for the purpose of providing additional functions for the organisation, increasing penalty for violation, and for related matters.

Vision

To improve life through standardisation and quality assurance.

Mission

To promote consumer confidence and global competitiveness of Nigerian products and services through standardisation and quality assurance.



SON – Objectives & Responsibilities

- **The aims and objectives of the SON include:**

- Preparation of standards relating to products, measurements, materials and processes among others, and their promotion at the national, regional and international levels;
- Certification of industrial products;
- Assistance in the production of quality goods;
- Improvement of measurement accuracy and circulation of information relating to standards.

Other Responsibilities include:

- Laboratory Services
- Management System Certification
- Import Permits
- Metrology Services
- Training
- Planning, Research and Statistics

Regulatory Practices

- **SONCAP** is a pre-shipment verification of conformity to Standards process used to verify that products to be imported into Nigeria are in conformity with the applicable NIS or approved equivalents, and technical regulations before shipment.
- **MANCAP** was put in place by Standards Organisation of Nigeria (SON) in 2006 to ensure that all manufactured products conform to the relevant Nigerian Industrial Standards (NIS) prior to sales in the markets or export. The scheme is aimed at protecting genuine manufacturers against unhealthy practices and provides consumers with confidence that products manufactured in the country are fit, safe and meet the intended use.

The Institute of Public Analysts of Nigeria (IPAN)

- The Institute of Public Analysts of Nigeria (IPAN) is a parastatal under the Federal Ministry of Health, is the regulatory body agency of the profession of Public Analysts established by Decree No. 100 of 1992 now IPAN Act Cap 1.16 LFN 2004 to train, examine, register Public Analysts and regulate their practice.



IPAN – Vision and Mission

- **VISION**

- To develop excellent professional scientific analysts who would act as catalysts for the industrial development of Nigeria and develop practices that would attain international reference status in the analysis of consumer products for the health and economic well-being of mankind.

- **MISSION**

- Public Analysts shall use best practices to carry out their scientific and technical roles in health and the environment to promote technological advancement and economic well-being of the nation.

Who is a Public Analyst?

- Section 14 (1) of IPAN Act states as follows: “a person shall be deemed to practice as a public analyst if, in consideration of remuneration to be received, and whether by himself or in partnership with any person, he:-
 - (a) engages himself in the practice of public analysis or holds himself out to the public analyst or
 - (b) renders professional service or assistance in or about matters of principle or detail relating to public analysis
 - (c) renders any other service which may by regulations made by the council, with the approval of the Minister, be designated as service constituting practice as public analyst.
- Section 14 (2) of IPAN Act provides that “a person registered as a member shall be eligible to practise the analysis of **water, chemicals, food, drugs, chemically and biologically-based consumer products, cosmetics and medical devices** and a certificate issued under the hand of a registered member shall constitute sufficient evidence as to the validity of the contents in any court of law or tribunal provided that the laboratory where the analysis was effected has been designated, registered and fully licensed by the appropriate authority” which is the Institute of Public Analysts of Nigeria.

IPAN – Mandate

- Determining what standards of knowledge and skill are to be attained by the persons seeking to practice as Public Analysts and managing those standards from time to time as circumstances may permit.
- Training and registration of Public Analysts.
- Regulation of the practice of Public Analysts by issuing guidelines on ethics and professional practice, review of such guidelines from time to time.
- Registration and regulation of analytical laboratories and carrying out other functions to ensure compliance with approved standards of practice.
- Apply sanctions for professional misconduct by members of the Institute.
- Provide library for research and the advancement of knowledge of members and the public.
- Creation of fora where Public Analysts meet to discuss matters affecting the profession.
- Co-ordination of information relevant to the profession and dissemination amongst Public Analysts.
- Standardization of analytical methods and development of new ones.
- Co-operation with relevant organisations whose objectives border on:
 - Standardization of consumer products.
 - Control of regulated products such as Food, Drugs, Cosmetics, Medical Devices, Water and Chemicals.
- Protection of the environment from hazardous substances.
- Participation in National Planning and Development.



Public Analysts – Roles in Product Quality

- Environmental Impact Assessment
- Environmental Audit Report
- Analysis for Regulatory purposes – Port Clearance, Product Registration
- Training and Consultancy
- Product Analysis for CAPA, Cost Transformation, NPD, EPD
- Audits and Assessments
- Process Implementation

Important Characteristics of a Quality Professional

- **Don't show off technical knowledge**
- **The best quality professionals are the customers**
- **Communication at all levels**
- **Be hands-on: Go to the *gemba*, observe, and do**
- **Continuously improve**
- **Ability to execute or implement**
- **Understand and speak the language of the business**
- **Thorough and meticulous**
- **Passion**
- **Personal discipline and integrity**
- **Use appropriate tools**
- **Help create a culture of seeing problems as opportunities**
- **Give and share credit for results**
- **Influencing skills**
- **Strategic thinking**
- **Eye for detail**
- **Be practical and results-oriented**
- **Be fair and objective**
- **Set high expectations and deliver them**
- **Friendly Manner**
- **Don't retro-fit analysis**

Thank You



Questions