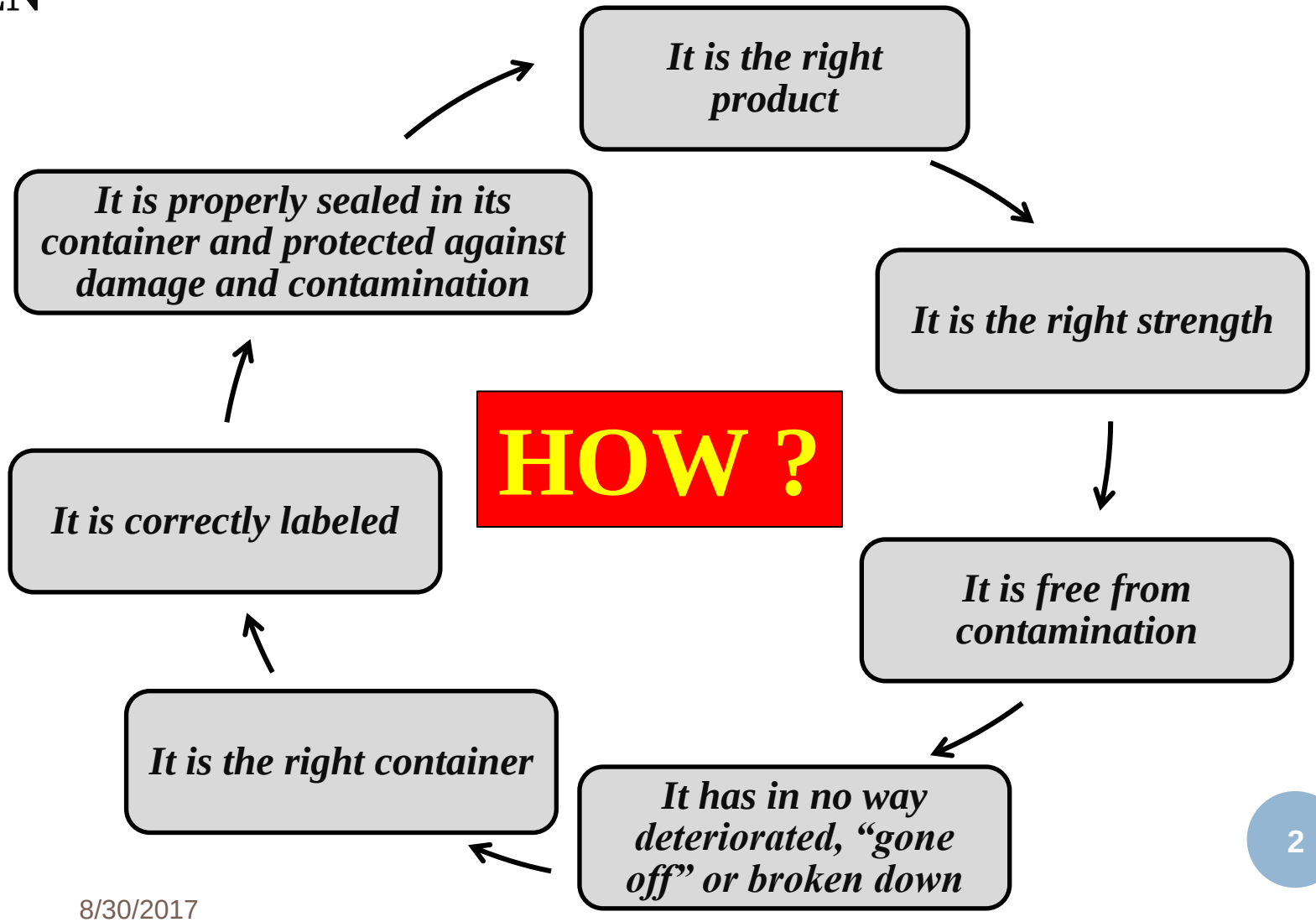
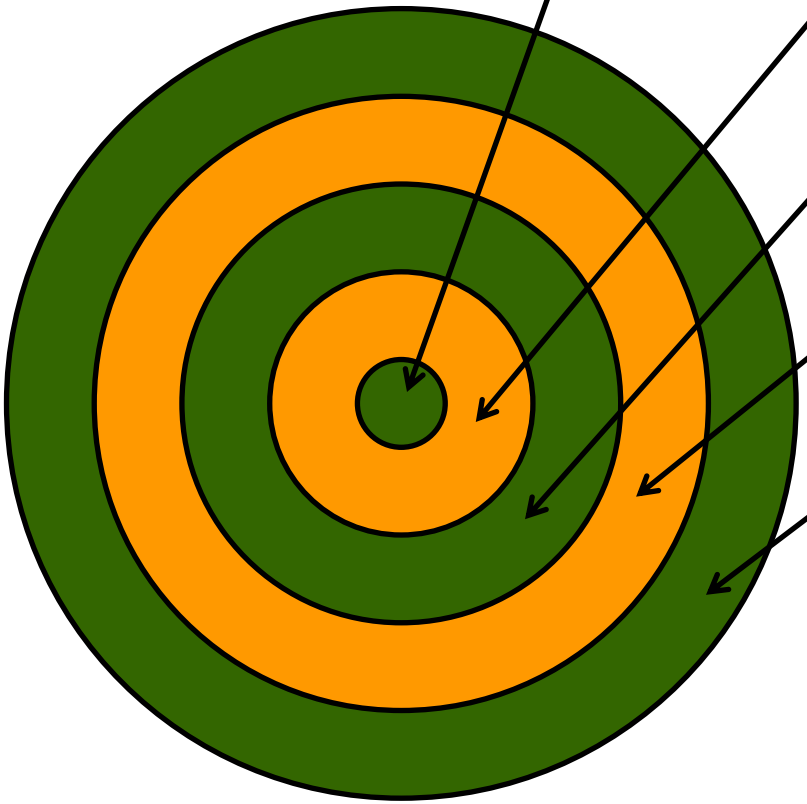
Quality Management System

MEDICINAL PRODUCT IS FIT FOR ITS PURPOSE ONLY WHEN



"BUSINESS PURPOSES"



Realizing its existence permanently

continuous customer satisfaction,

ensure long-term, healthy profit for the business and

promote the growth

include

- **the satisfaction of employees,**
- **convenience to the societies**
- **improved profits to business associates, shareholders and all other parties related to the business.**

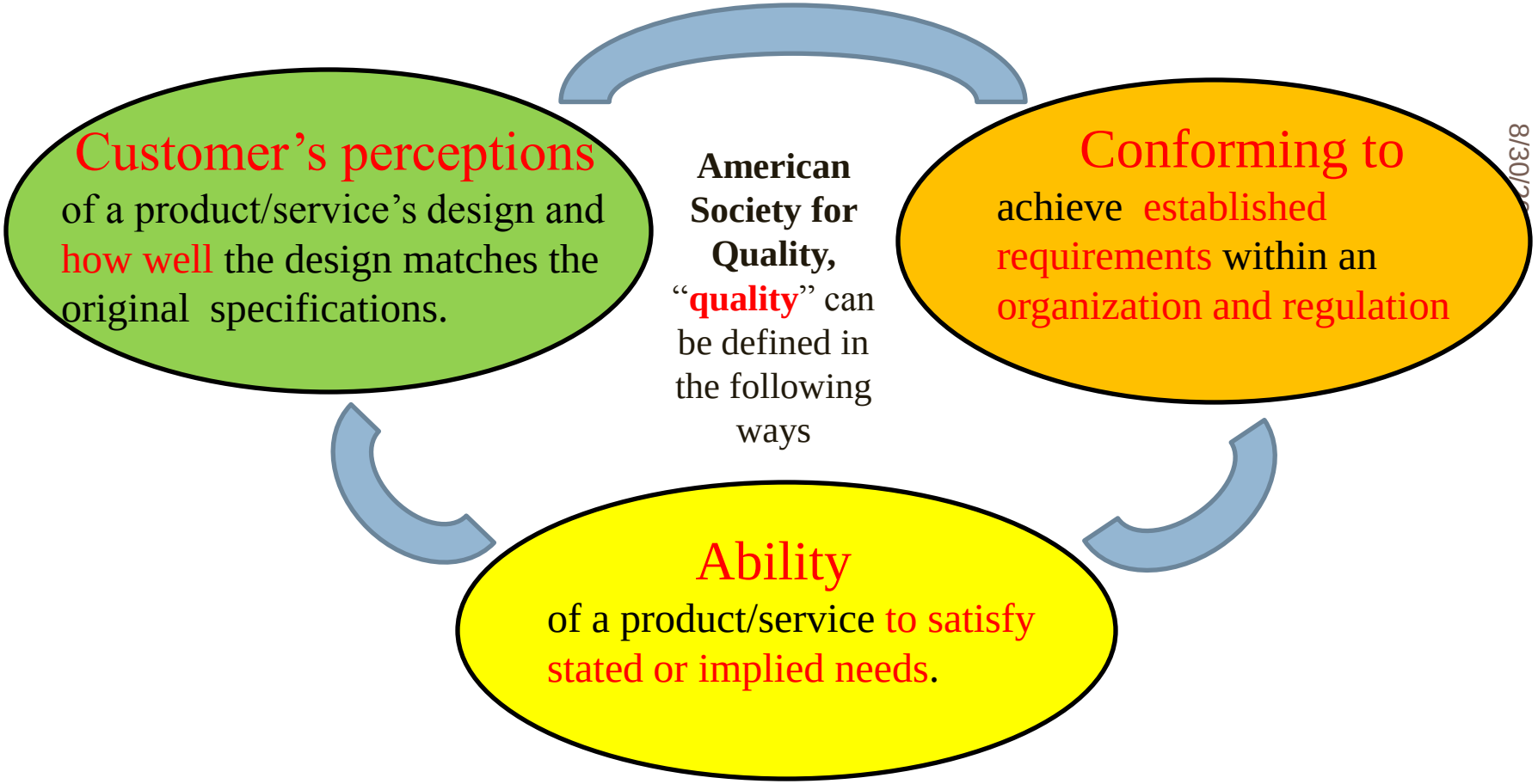
Through "Systematic activities"

"SYSTEMATIC ACTIVITIES"

Organized activities performed based on

1. Strong sense of **mission** and **strong leadership** of top management in order to achieve the corporate mission (objectives)
2. Clear mid and long-term **vision** and **strategy**
3. Appropriate **quality policy** and strategy

WHAT IS QUALITY?



Joseph M. Juran in the 70th defined quality as **"fitness for use,"** meaning **the users of products or services** should be **able to relay on that product or service 100 percent** of the time **without any worry of defects**.

If it is true, the product could be classified as "fit for use"

WHY IS QUALITY IMPORTANT?

- Business success may simply be the extent [illegible] your organization can produce a higher-qua[illegible] service at a competitive price than your c[illegible] do

- When **quality** is the key [illegible] managing Quality through **Qu[illegible]s/QMS** will allow organizati[illegible]
  - keep up [illegible]ity levels,
  - meet [illegible]ent for quality,
  - retain e[illegible] competitive compensation programs,
  - keep up wit[illegible] latest technology

QUALITY is NOT JUST PRODUCT QUALITY or QUALITY CONTROL

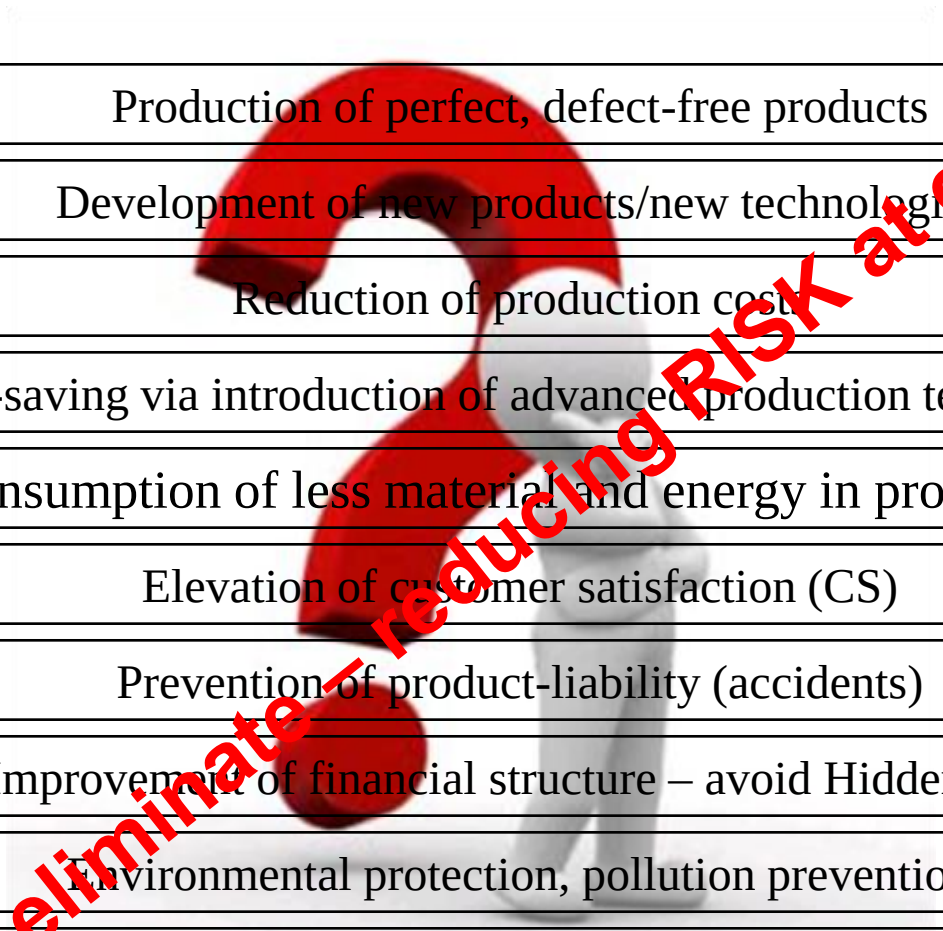
Purpose of Quality Management

Systematic activities of operating the functional units of a company effectively and efficiently to

- **supply goods and services of quality** satisfactory to **customers** at an acceptable time and at right price
- contribute to attaining **business purposes**

TARGET TOTAL QUALITY MANAGEMENT SYSTEM

1	Production of perfect, defect-free products
2	Development of new products/new technologies
3	Reduction of production cost
4	Labor-saving via introduction of advanced production technologies
5	Consumption of less material and energy in production
6	Elevation of customer satisfaction (CS)
7	Prevention of product-liability (accidents)
8	Improvement of financial structure – avoid Hidden cost
9	Environmental protection, pollution prevention
10	Tributes to mankind, elevation of employee satisfaction (ES)



avoid - eliminate – reducing RISK at every level

Why QMS is required ➔ HOW ?

Quality Management System

SURVEY

conducted by
the **Defense Evaluation Research Agency** (DERA)

- ca.96% of respondents said they believed their system contributed to meeting the business goals.
- However, ca.72% responded that their organization did not measure this contribution.

What Is a Quality Management System?

- A quality management system is **a management technique** used to communicate to employees what is required to produce the desired quality of products and services and to influence employee actions to complete tasks according to the quality specifications.

- A QMS can be defined as:

  "A set of coordinated activities to direct and control an organization in order to continually improve the effectiveness and efficiency of its performance."

- ***What Purpose Does a Quality Management System Serve?***
  - ✔ Establishes a vision for the employees.
  - ✔ Sets standards for employees.
  - ✔ Builds motivation within the company.
  - ✔ Sets goals for employees.
  - ✔ Helps fight the resistance to change within organizations.
  - ✔ Helps direct the corporate culture.

PURPOSE OF QUALITY MANAGEMENT SYSTEM

To "operate the whole units of a company effectively and efficiently"

Quality Assurance System as core

Integrate control systems, such as costs, mass-production delivery, environment and safety

Employees in all divisions and at all stratums join forces to carry on the work

For that purpose

"**Customers**" are Purchasers stakeholders (including users, industrial users, consumers, beneficiaries, etc.)

"**Quality**" is

Usefulness | Reliability | Safety

with effect on third parties, society, environment and future generations taken in consideration.

"Goods / Service" are all other things supplied to customers along with goods and services including:

Systems **Software**

Energy **Information**

"Supply" means

The whole process of activities to deliver goods and services to customers

Development — *Sales* — *Manufacture* — *Distribution*

Maintenance and after-sales service, disposal or recycling

Support core technologies / speed / vitality, with due respect to mankind

Foster personnel

By using appropriate scientific methods and information technologies

Use facts as basis to plan, implement, evaluate and treat processes and work (PDCA)

Improve management

Restructuring of management system

THE BENEFIT WHEN QMS IS IMPLEMENTED CORRECTLY

An organization will benefit from establishing an effective quality management system (QMS).

- The cornerstone of a quality organization is the concept of the customer and supplier working together for their mutual benefit.
- For this to become effective, the customer-supplier interfaces must extend into, and outside of, the organization, beyond the immediate customers and suppliers.
- These activities interact and are affected by being in the system, so the isolation and study of each one in detail will necessarily lead to an understanding of the system as a whole.

➔ **The main thrust of a QMS is in defining the processes, which will result in the production of quality products and services, rather than in detecting defective products or services after they have been produced.**

Quality Management System

The benefit when QMS is implemented correctly

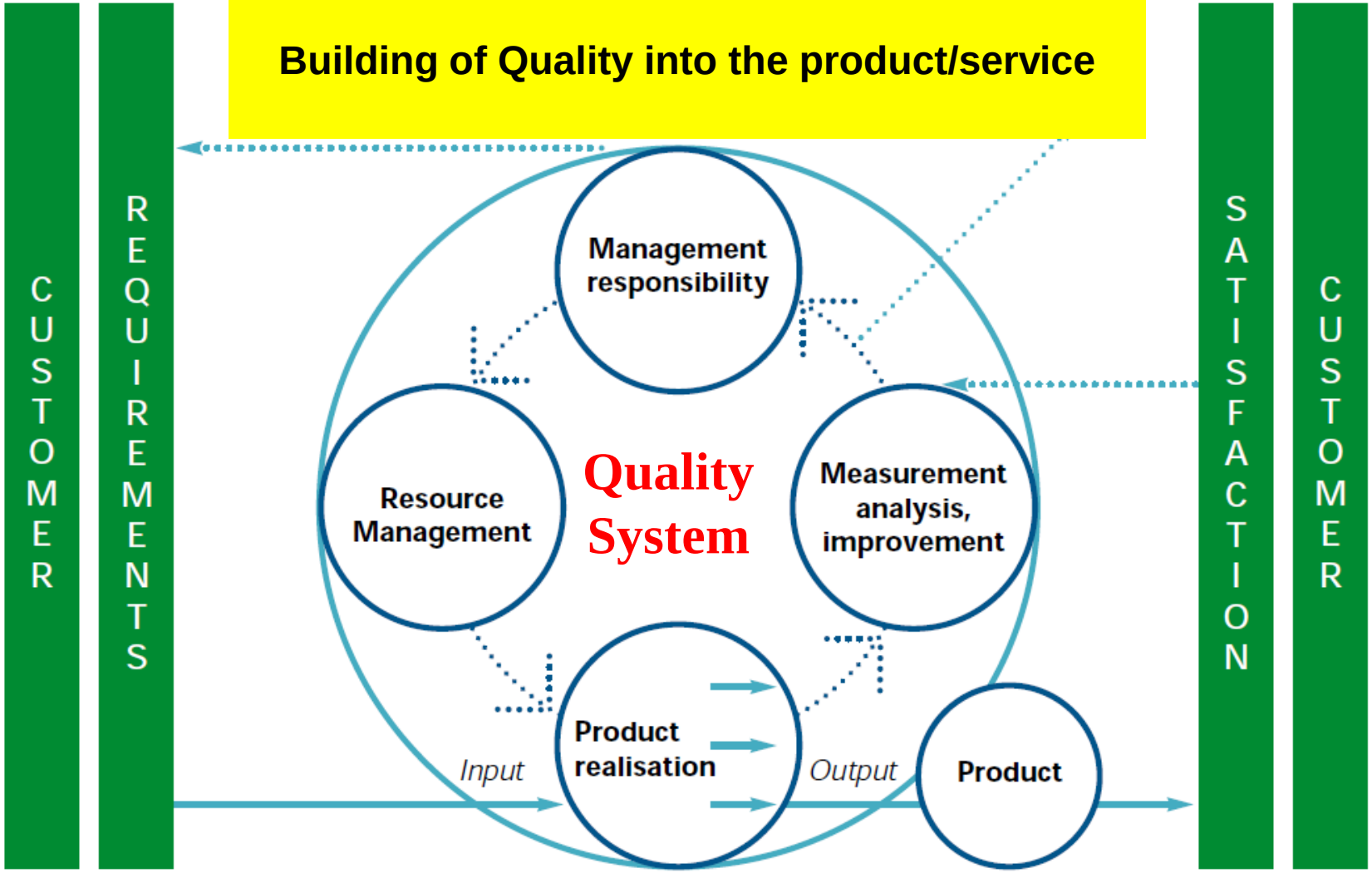
- is needed in all areas of activity, whether large or small businesses, manufacturing, service or public sector.
- A good QMS will:
  - Set direction and meet customers' expectations
  - Improve process control
  - Reduce wastage
  - Lower costs
  - Increase market share
  - Facilitate training
  - Involve staff
  - Raise morale

Concept to Build Quality System

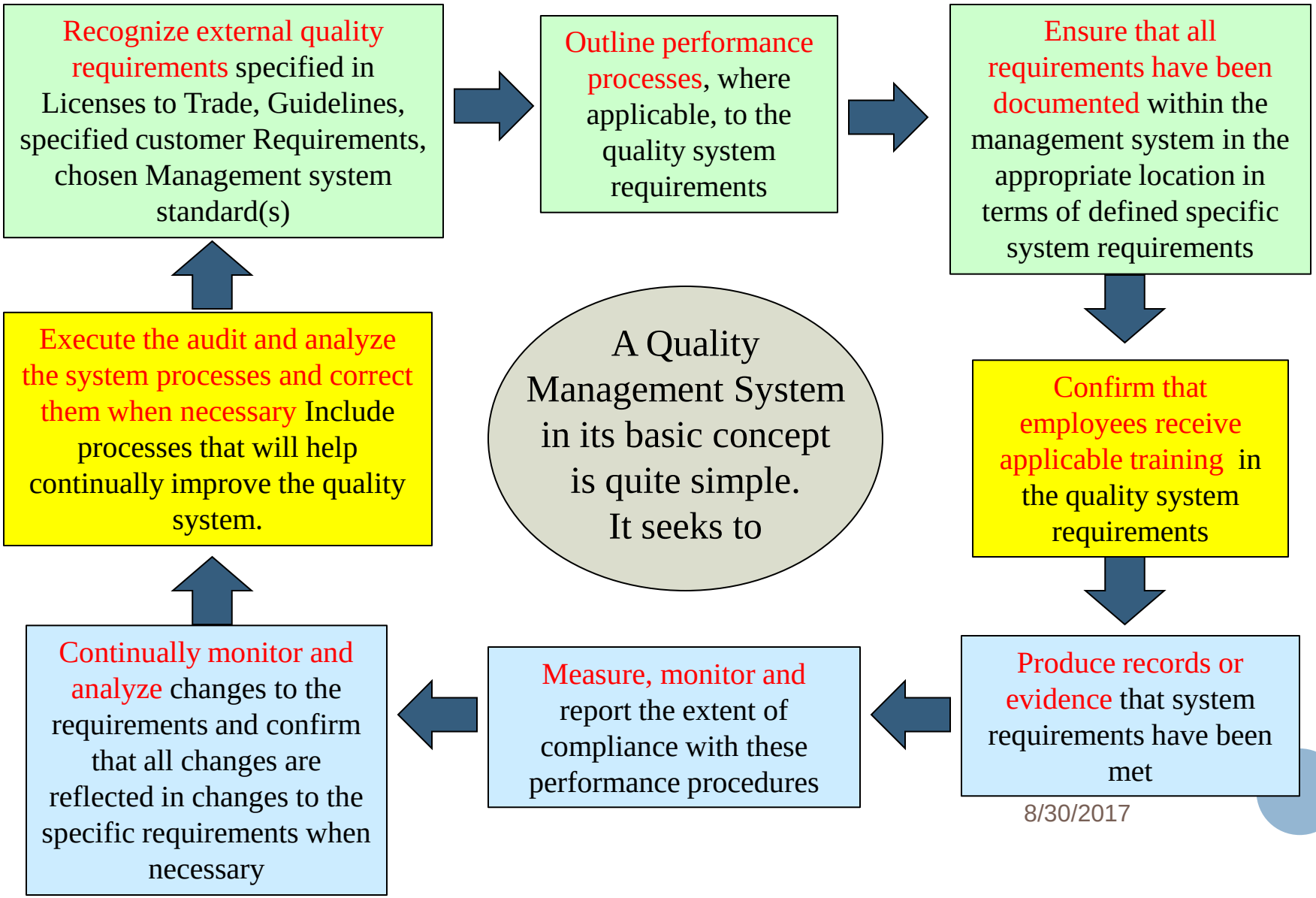
8/30/2017

THE CONCEPT OF TOTAL QUALITY MANAGEMENT SYSTEM

Building of Quality into the product/service



The Concept of Quality Management System



Quality Management System

- ISO 9001 series
- ISO 14000
- OSHAS 16000
- GMP
- etc.

- LEAN
- LEAN Six Sigma
- TPM
- HACCP
- GMP
- etc.

- ICH
- USP
- DIN ISO
- Textbook
- PDA, PQRI, ISPE etc

CHAPTER 1

PHARMACEUTICAL QUALITY SYSTEM

The holder of a Manufacturing Authorisation must manufacture medicinal products so as to ensure that **they are fit for their intended use**, comply with the requirements of the Marketing Authorisation or Clinical Trial Authorisation, as appropriate, and do not place patients at risk due to inadequate safety, quality or efficacy.

To achieve this quality objective reliably there must be a comprehensively designed and correctly implemented Pharmaceutical Quality System incorporating Good Manufacturing Practice and Quality Risk Management.

The basic concepts of Quality Management, Good Manufacturing Practice (GMP) and Quality Risk Management are inter-related. They are described here in order to emphasise their relationships and their fundamental importance to the production and control of medicinal products

CHAPTER 1

PHARMACEUTICAL QUALITY SYSTEM

1.1 **Quality Management** is a wide-ranging concept, which covers all matters, which individually or collectively influence the quality of a product. It is **the sum total of the organised arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use. Quality Management therefore incorporates Good Manufacturing Practice.**

1.2 **GMP** applies to the lifecycle stages from the manufacture of investigational medicinal products, technology transfer, commercial manufacturing through to product discontinuation. However the **Pharmaceutical Quality System can extend to the pharmaceutical development lifecycle stage as described in ICH Q10, which while, should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities.**

1.3 The size and complexity of the company's activities should be taken into consideration when developing a new Pharmaceutical Quality System or modifying an existing one. **The design of the system should incorporate appropriate risk management principles including the use of appropriate tools**. While some aspects of the system can be company-wide and others site-specific, the effectiveness of the system is normally demonstrated at the site level.

International Organization for Standardization (ISO)

- **ISO 9000 - Quality Management Systems – Fundamentals and vocabulary**
- **ISO 9001 - Quality Management Systems – Requirements**
- **ISO 9004 - Guidelines for performance improvement**

The ISO Series can form the means by which a holistic management system can be implemented, into which quality, health and safety and environmental responsibility can be integrated, with the audits carried out either separately or in combination.

ISO 9001

- ISO 9001 specifies the requirements for a QMS that may be used by organizations for internal application, certification or contractual purposes.

- The process approach is shown in the conceptual model from the ISO 9001 Standard,
  - recognizing that customers play a significant role in defining requirements as inputs, and
  - monitoring of customer satisfaction is necessary to evaluate and validate whether customer requirements have been met.

THE MAJOR CLAUSES AND SUB-CLAUSE ISO

- **Scope**
- **Normative reference**
- **Terms and definitions**
- **Quality Management System**
  - General requirements
  - Documentation requirements
- **Management responsibility**
  - Management commitment
  - Customer focus
  - Quality policy
  - Planning
  - Responsibility, authority and communication
  - Management review
- **Resource management**
  - Provision of resources
  - Human resources
  - Infrastructure
  - Work environment
- **Product realization**
  - Planning of product realization
  - Customer-related processes
  - Design and/or development
  - Purchasing
  - Production and service operations
  - Control of measuring and monitoring devices
- **Measurement, analysis and improvement**
  - General
  - Planning
  - Monitoring and measurement
  - Control of non-conforming product
  - Analysis of data
  - Improvement

QUALITY SYSTEM DESIGN

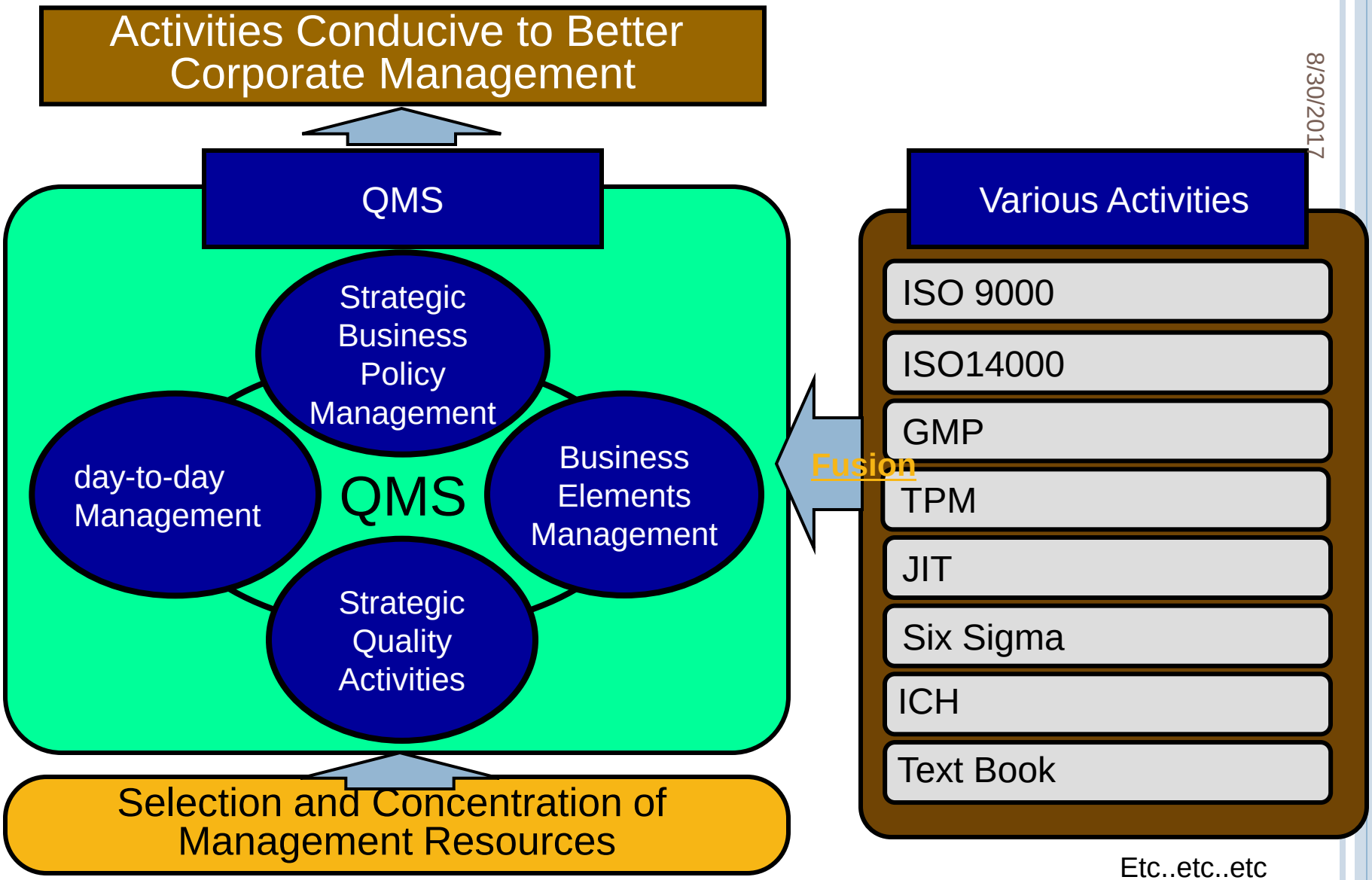
Will influence

- Foundation and building up Quality
  - Recognizing System➔ GMP, ISO, TPM etc
  - Developing Quality Management System (Personal, Supply chain, Purchasing, Product development, Production, QC, QA, Engineering)
  - Deployment of QMS
- Implementation
- Roles, Attitude and Behavioral
- Quality Risk Management
- Managing Cost of Quality ➔ Hidden Cost
- Management System Review

Roles of Management for Promoting **QMS**

(1) Take the initiative as the leader.
(2) Devise a good mechanism, refine and sophisticate it.
(3) Deploy aggressively activities for settling target, plan, issues and solving problems.
(4) Evaluate with the emphasis on processes.
(5) Formulate plans and policies (Q/EHS System and standard) and keep track of their implementation, monitoring and progress status.
(6) Clarify the roles and responsibilities of team members.
(7) Make no excuses for delay in implementation or lack-inadequate performance.
(8) Initiate RISK MAPPING for all general activities
(9) Initiate and Lead proper RISK MANAGEMENT SYSTEM at every step of activity
(10) Formulate and establish BCP

QMS as All-Around Activities



A. Set up QMS

8/30/2017

The adoption of a QMS

- Has to be a strategic decision of an organization, and is influenced by varying needs, objectives, the products/services provided, the processes employed and the size and structure of the organization.

- A QMS must ensure that the products/services conform to customer needs and expectations, and the objectives of the organization.

- Issues to be considered when setting up a QMS include its:
  1. **Design and Build**
  2. **Deployment and Control**
  3. **Measurement and Review**
  4. **Improvement**

1. DESIGN AND BUILD

includes the structure of the quality management system, the process and its implementation.

- It's design must be led by senior managers to suit the needs of the organization, and this is ideally done using a framework to lead the thinking.

- Design of the **QMS** should come from determining
  - **organization's core processes,** and
  - **well-defined goals** and **strategies**, and
  - be **linked to the needs of one or more stakeholders**.

- The process for designing and building the **QMS**
  - **Must be clear,** with **the quality function playing a key role**, but
  - **Involvement and buy into** the system must also come from all other functions.

2. Deployment and Control

Deployment and implementation is best achieved using process packages, where each core process is

- broken down into sub-processes, and
- described by a combination of documentation, education, training, tools, systems and metrics.
- electronic deployment via Intranets is increasingly being used

Control of the QMS will depend on the size and complexity of the organization

- a site-based system, and local audits and reviews are essential even if these are supplemented by central reviews.
- Local control, where possible, is effective, and good practice is found where
  - key stakeholders are documented within the process and
  - where the process owner could and allowed to control all of the process.
- Ideally, process owners/operators are involved in writing procedures.

3. Measurement and Review

Measurement is carried out to determine the effectiveness and efficiency of each process towards attaining its objectives.

- It should include the contribution of the QMS to the organization's goals; this could be achieved by measuring the following:
  - Policy definition completeness
  - Coverage of business
  - Reflection of policies
  - Deployment
  - Usage
  - Whether staff find the QMS helpful in their work
  - Speed of change of the QMS
  - Relevance of QMS architecture to the job in hand
- A form of scorecard deployed through the organization down to individual objective level can be employed, and the setting of targets at all levels is vital.

Review of the effectiveness, efficiency and capability of a QMS is vital, and the outcome of these reviews

- should be communicated to all employees.
- Reviewing and monitoring should be conducted whether or not improvement activities have achieved their expected outcomes.

4. IMPROVEMENT

- **Improvement should follow as a result of the review process, with the aim of seeking internal best** practice.
- It is part of the overall improvement activities and an integral part of managing change within the organization.
- **ISO 9000 contains 8 quality management principles**, upon which to base an efficient, effective and adaptable QMS.

  They are applicable throughout industry, commerce and the service sectors:

1. Customer focus
2. Leadership
3. Involving people
4. Process approach
5. Systems approach
6. Continual improvement
7. Factual decision making
8. Mutually beneficial supplier relationships

B. Assessment of a Quality Management System

Audit, and Review

8/30/2017

Assessment of a Quality Management System

Pengkajian ulang Quality Management System

1. Audit internal atau eksternal
   - Sistematik dan periodik
   - Pelaksanaan tindakan korektif
   - Terdokumentasi
2. Quality Management Review

THE GENERIC STEPS INVOLVED IN AN AUDIT

- **Initiation**
  - Scope
  - Frequency
- **Preparation**
  - Review of documentation
  - The program
  - Working documents
- **Execution**
  - Opening meeting
  - Examination and evaluation
  - Collecting evidence
  - Observations
  - Close the meeting with the auditee
- **Report**
  - Preparation
  - Content
  - Distribution
- **Completion**
  - Report
  - Submission
  - Retention

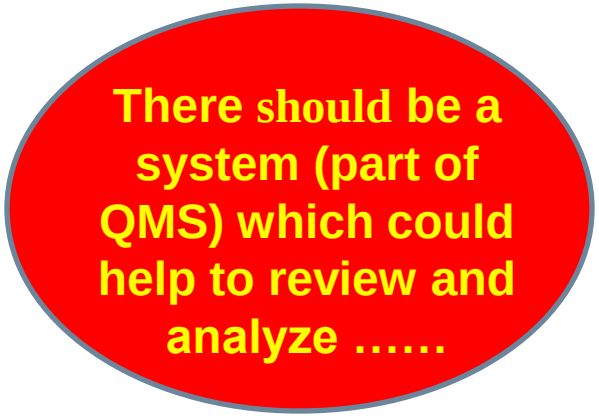
In addition,

- the procedures for conducting audits and reviews and the results from them should be documented, and also be subject to review.
- Internal system audits and reviews should be positive and conducted as part of the preventative strategy, and
- not as a matter of expediency resulting from problems.

2. QUALITY MANAGEMENT SYSTEM REVIEW

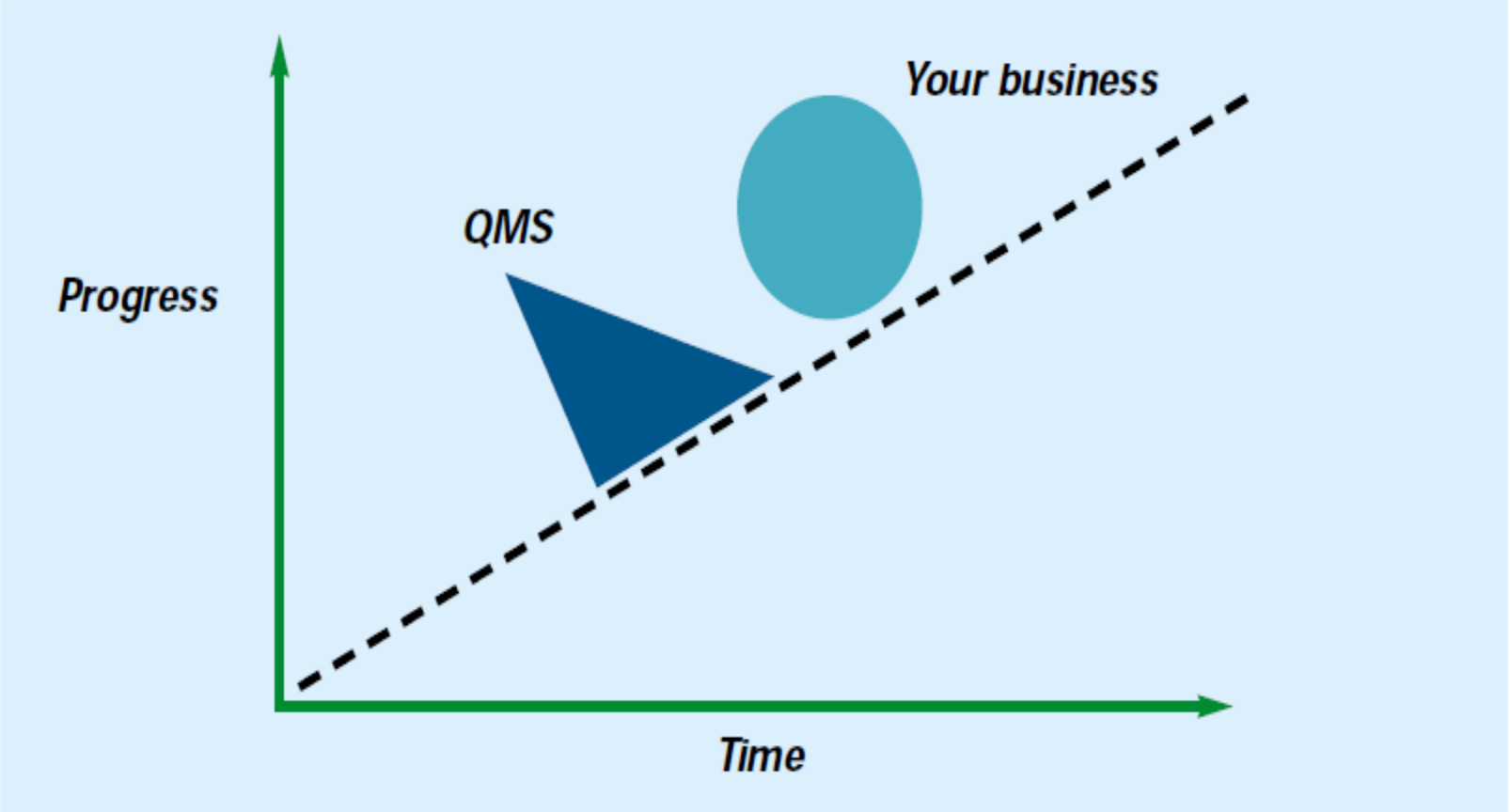
should take place, possibly once - twist a year, which should cover

- Results of audits
- Customer feedback
- Process and product conformity
- Deviation that could effect the Quality
- Changes that could effect the QMS
- Status of Corrective and Preventative Actions
- Follow up actions from previous management reviews
- Recommendations for improvements
- Outputs should include:
  - Improvements to the QMS and processes
  - Improvements of a product related to customer requirements
  - Resource needs



PENUTUP

The benefits of a Good Quality Management System



THE BENEFITS OF A QMS

- A fully documented QMS will ensure that two important requirements are met:
  - The customers' requirements – confidence in the ability of the organization to deliver the desired product and service consistently meeting their needs and expectations.
  - The organization's requirements – both internally and externally, and at an optimum cost with efficient use of the available resources – materials, human, technology and information.
- These requirements can only be truly met if objective evidence is provided, in the form of information and data, to support the system activities, from the ultimate supplier to the ultimate customer.
- A QMS enables an organization to achieve the goals and objectives set out in its policy and strategy.
- It provides consistency and satisfaction in terms of methods, materials, equipment, etc, and interacts with all activities of the organization, beginning with the identification of customer requirements and ending with their satisfaction, at every transaction interface.
- It can be envisaged as a "wedge" that both holds the gains achieved along the quality journey, and prevents good practices from slipping

TERIMA KASIH