



General
**MEMBERSHIP
MEETING**

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Internal Audit's Value in Quality
Management

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Quality Concepts

What is QUALITY?

“Degree to which a set of inherent characteristics fulfils requirements”

Facts about QUALITY?

Quality is a TERMINATOR

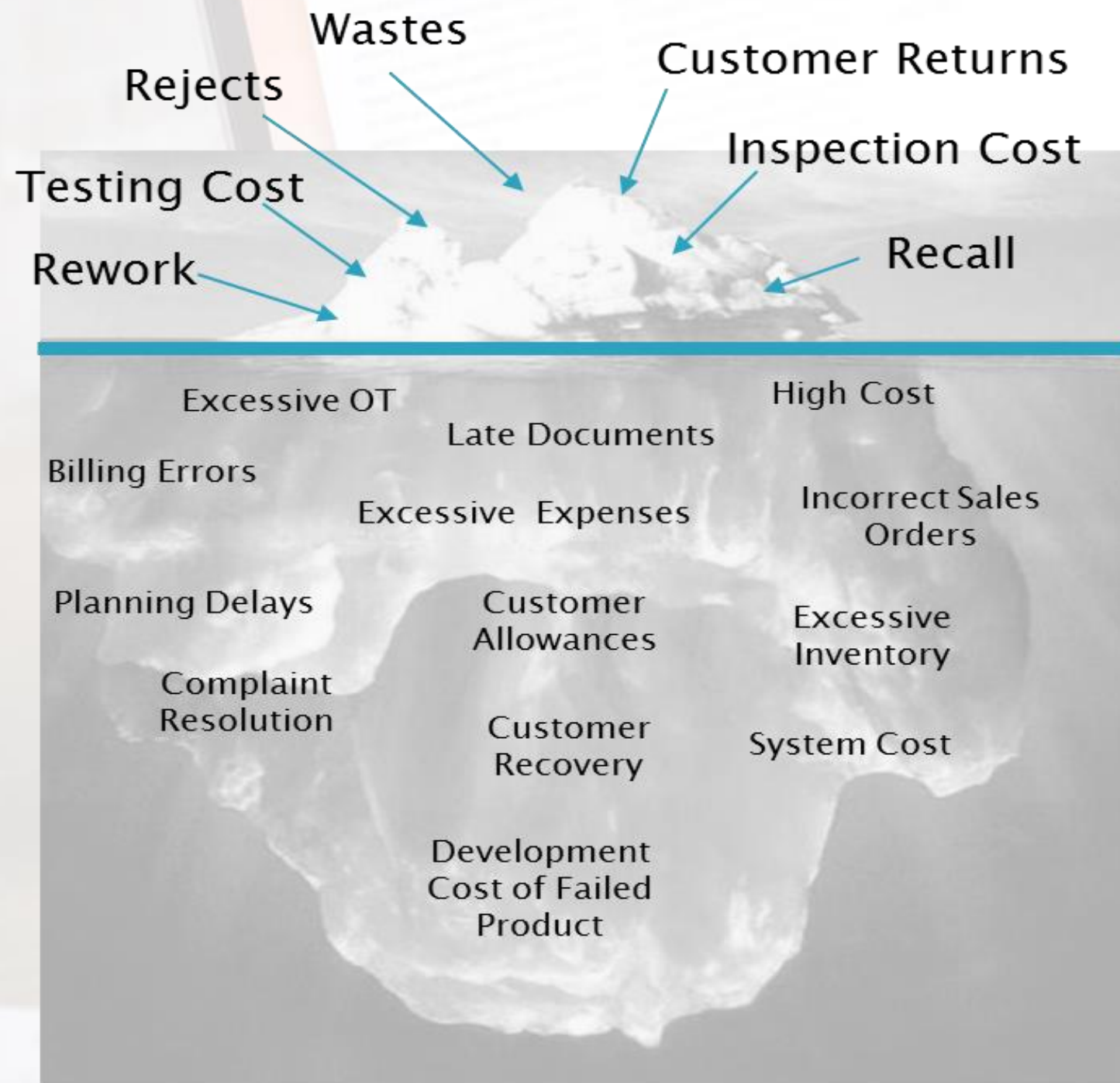
Quality is a PEACE MAKER

Quality is an EMANCIPATOR

Quality is a WINNING GLOBAL STRATEGY

Quality Concepts

COST of POOR QUALITY (COPQ)



Traditional Cost of Poor Quality (4.0 – 5.0% of Sales)

When quality costs are initially determined, the categories included are the visible ones as depicted in the iceberg.

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

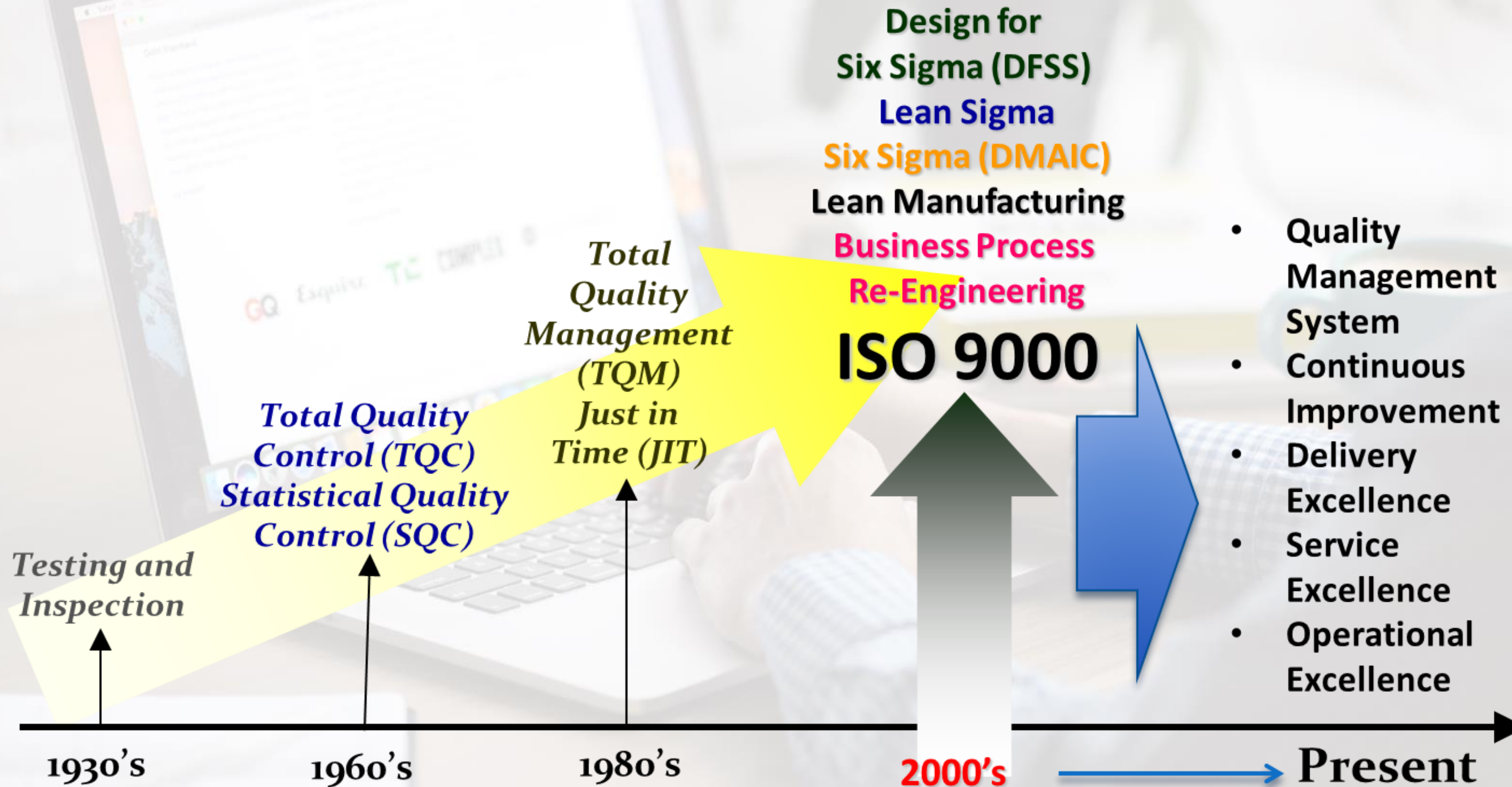
Hidden COPQ:

The costs incurred to deal with these problems

True COPQ:

Cost of Poor Quality (COPQ) is now 15–20% of the total sales

Evolution of Quality Practices



Quality Management System

“A quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization’s activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.”

Quality Management System (QMS) Through the Years

ISO 9001:1987/1994

- *Prescriptive: clause - by - clause*

ISO 9001:2000/2008

- *Process approach less documentation*

ISO 9001:2015

- *Performance- based*
- *Process + Risk based thinking+ PDCA*
- *Forecast life span till 2030 !!*

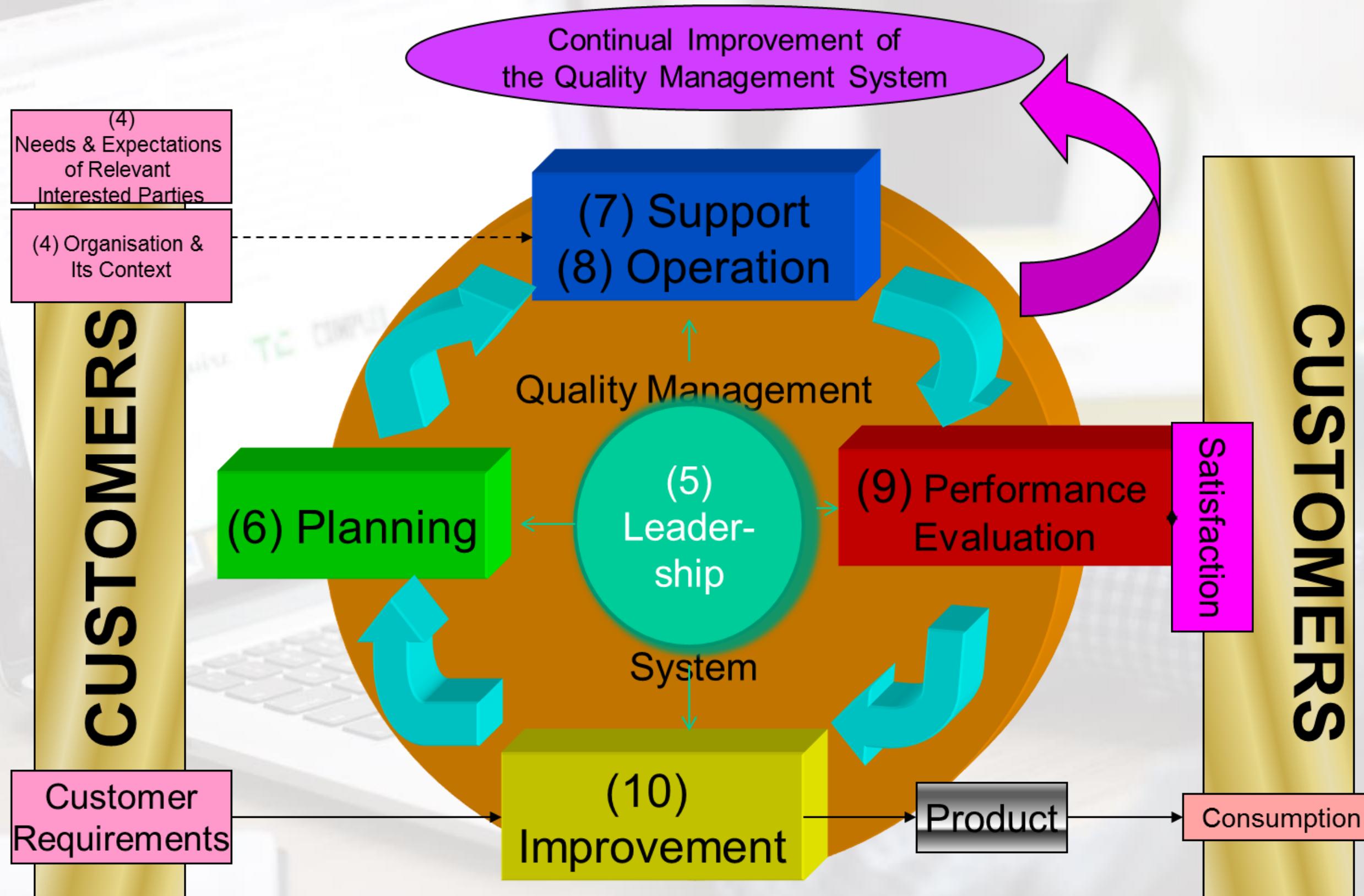


The Foundation: PDCA Cycle

Seven Quality Management Principles



The Quality Management System Model



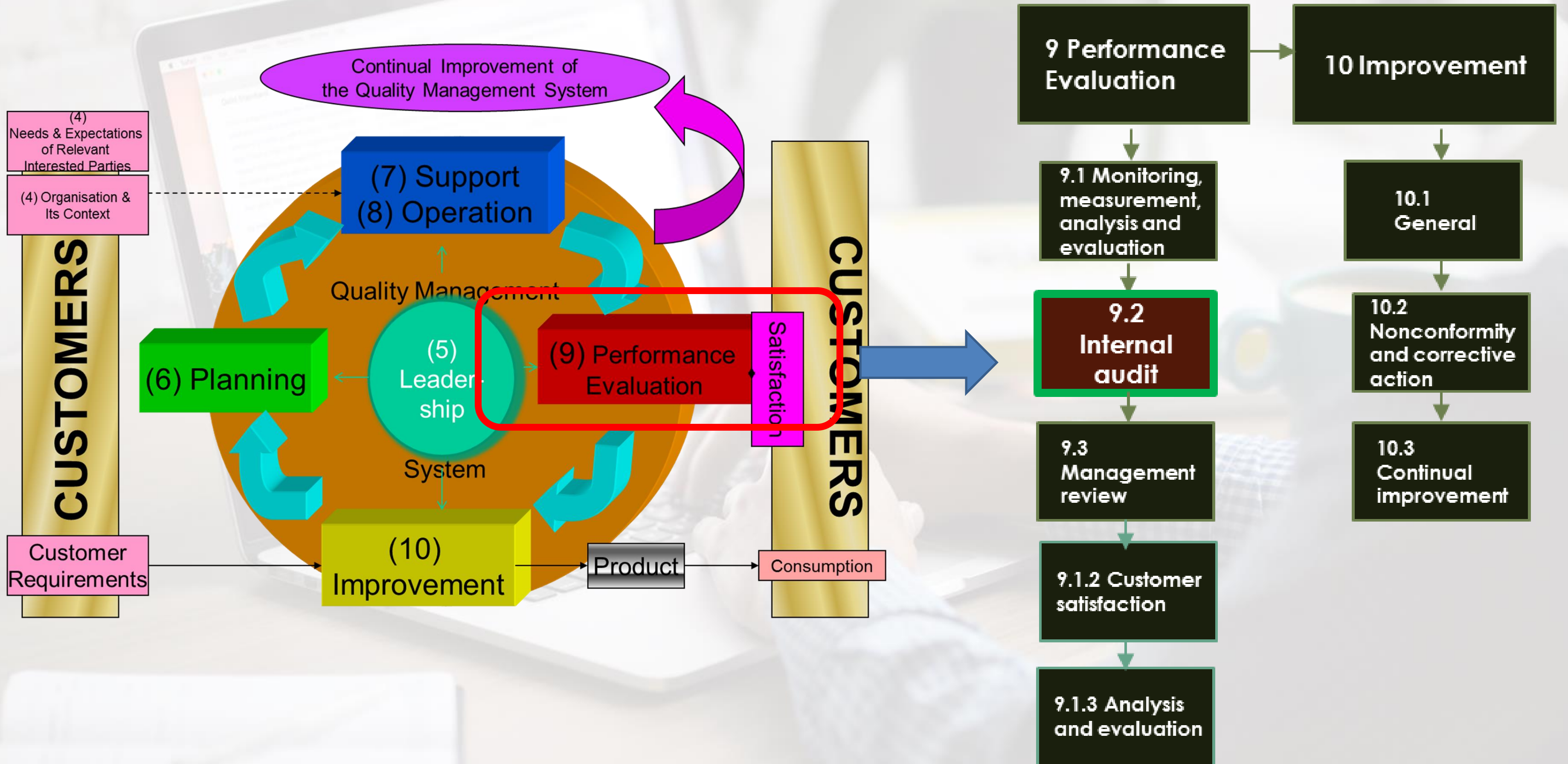
Core Concepts for ISO 9001:2015

- Identify the **processes** needed to achieve the planned results
- Continually monitor the **risks** (“Risk-based thinking”)
 - Understanding the “Cause and effects”
- Manage the processes and the system using **“PDCA”**



A person is sitting at a desk, working on a laptop. The laptop screen displays a Quality Management System (QMS) interface with various charts and data. The person's hands are on the keyboard. In the background, there is a white mug and some papers. The overall scene is a professional office environment.

How can you keep the sanctity and integrity of your Quality Management System?



Types of Audits in QMS



INTERNAL AUDIT

Organization Auditing its own QMS



EXTERNAL AUDIT

Organization Auditing its Supplier



3RD PARTY AUDIT

Certifying Body Audit

QMS Internal Audit

REASONS FOR QMS INTERNAL AUDIT:

- Requirement of the standards (ISO 9001)
- Preparation for the Certifying Body Audit
- Source of information for use by management
- Powerful tool for continual improvement through:
 - Employee involvement
 - Communication
 - Employee awareness, etc.

OBJECTIVES OF QMS INTERNAL AUDIT:

- ❑ The objective of internal audit is to assess the status of the System from the point of view of adequacy of documents (Intent), compliance and effectiveness.
- ❑ Nonconformities could arise out of two reasons:
 - System deficiencies
 - Human errors

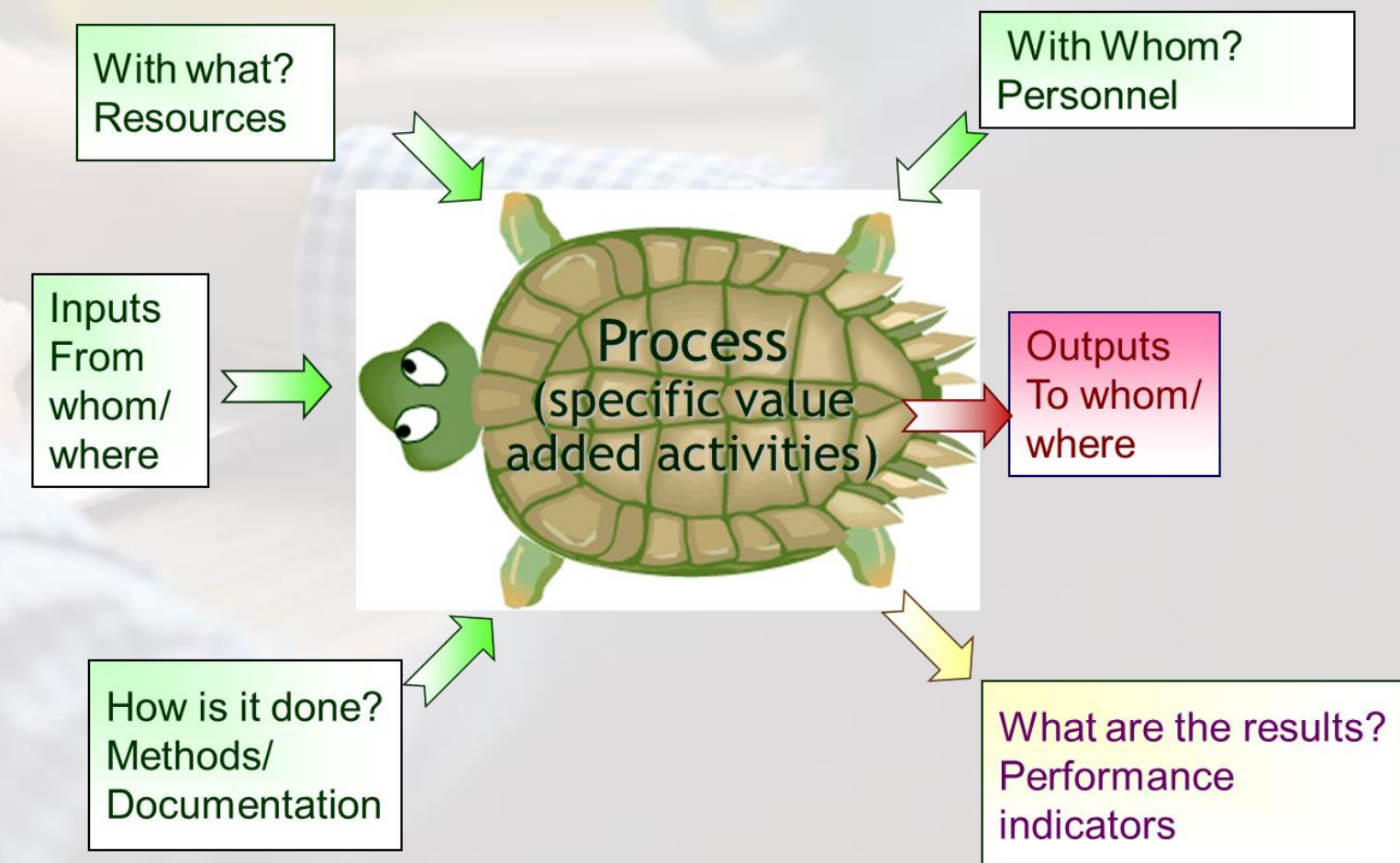
“Internal audits should be aimed at identifying system deficiencies. “

Process Approach QMS Internal Auditing

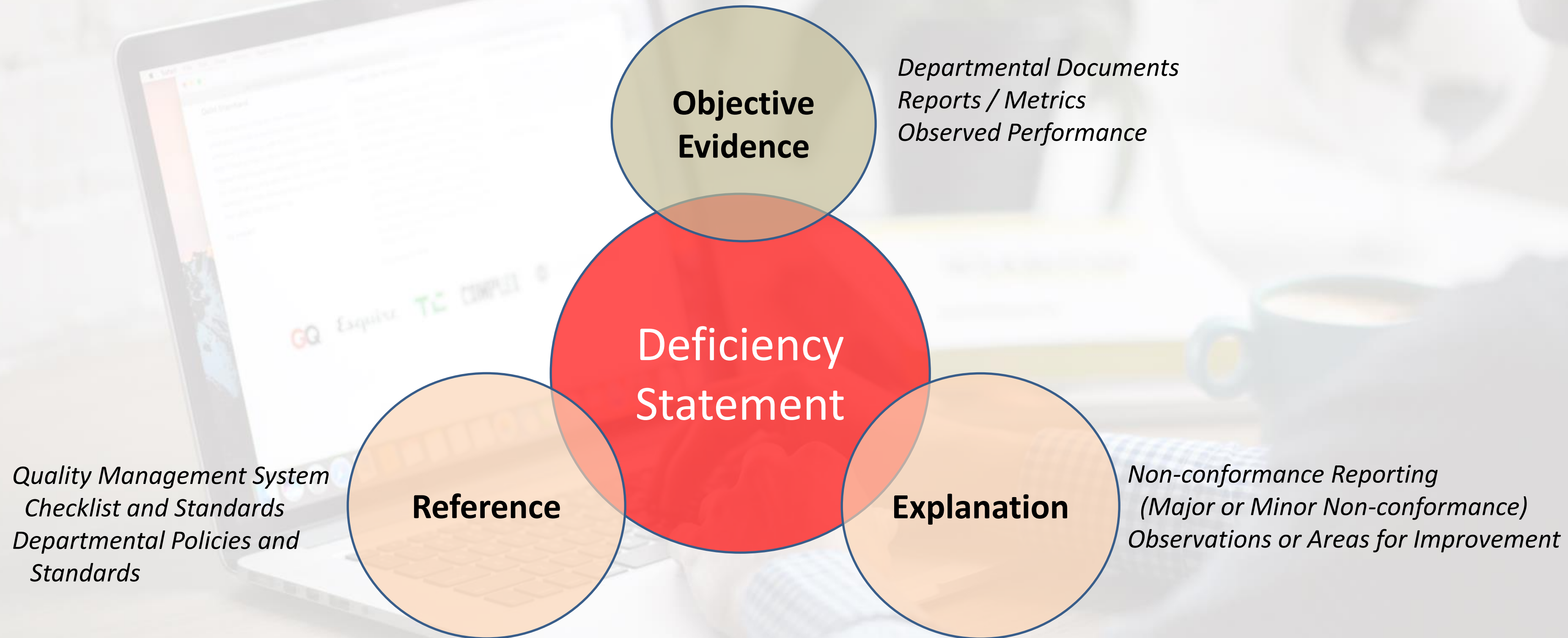
The process approach to auditing focuses on reviewing the sequence and interaction of processes and their inputs and outputs. It analyzes the management system not just as if it were a set of documented procedures, but rather as an active system of processes that addresses business risk and its applicable requirements.

The main elements that a process-approach audit reviews are:

- Process Owners
- Inputs and Outputs of the process
- Resources
- Methods/ Procedures/ Instructions
- Controls/ Measurements/ Metrics
- Documents/Records
- Efficiencies/ Effectiveness



The Audit Reporting



Internal Business Controls and QMS

The Sarbanes-Oxley Act of 2002 is a law the U.S. Congress passed on July 30 of that year to help protect investors from fraudulent financial reporting by corporations.

Section 404 of the SOX Act of 2002 requires that management and auditors establish [internal controls](#) and reporting methods to ensure the adequacy of those controls. Most organizations use the Committee of Sponsoring Organizations of the Treadway Commission (COSO) guidance to satisfy this requirement.

COSO OBJECTIVES

- Effectiveness and efficiency of operations
- Reliability of financial reporting
- Compliance with laws and regulations

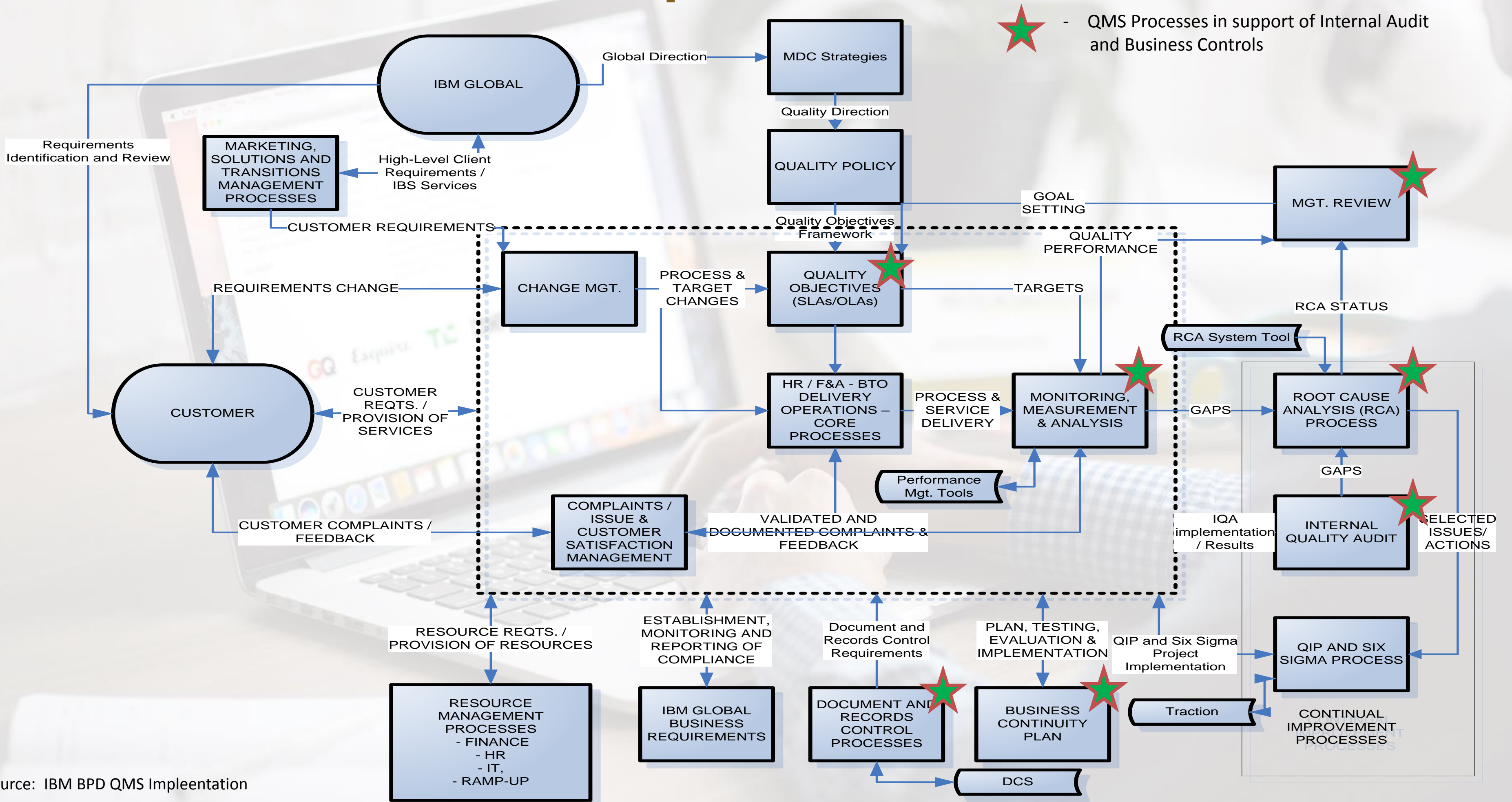
COSO ELEMENTS

- Control environment
- Information and communication
- Risk assessment
- Monitoring
- Control activities

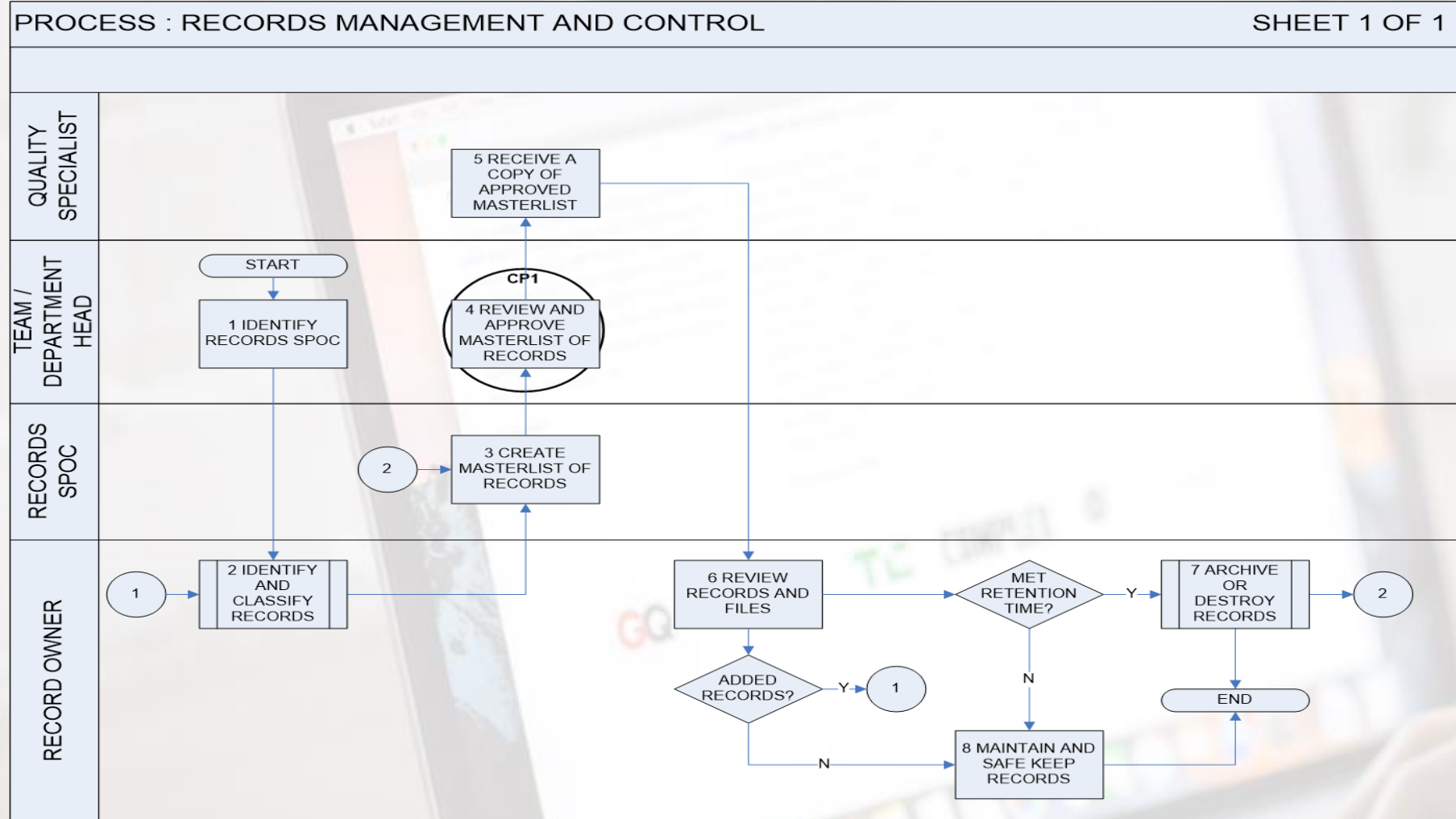
Internal Business Controls and QMS

QMS 	CONTEXT OF THE ORGANIZATION	LEADERSHP	PLANNING	SUPPORT	OPERATION	PERFORMANCE EVALUATION	IMPROVEMENT
COSO 							
CONTROL ENVIRONMENT	Scope and Processes of QMS	Leadership Commitment Customer Focus	Plan for Changes in the Organization	People Competence Infrastructure Ops Environment Resource Management Knowledge Mgmt	Operational planning and control Control of externally provided products, services and processes		
INFORMATION AND COMMUNICATION		Organizational Roles and Responsibilities Communicating Quality Policy			Organizational Communication Customer Communication		Communicate Non-conformance
RISK ASSESSMENT		Establishing the Quality Policy	Address Risks Achievement of Quality Objectives		Review of Products and Services	Management Review	Analysis of Non-conformities
MONITORING				Monitoring of Resources		Performance Measurement, Analysis and Monitoring	Monitor Continuous Improvement
CONTROL ACTIVITIES					Documented Tasks Document Control Control of non conforming outputs	Internal Audit	Corrective and Preventive Action Continuous Improvement

QMS Framework Example

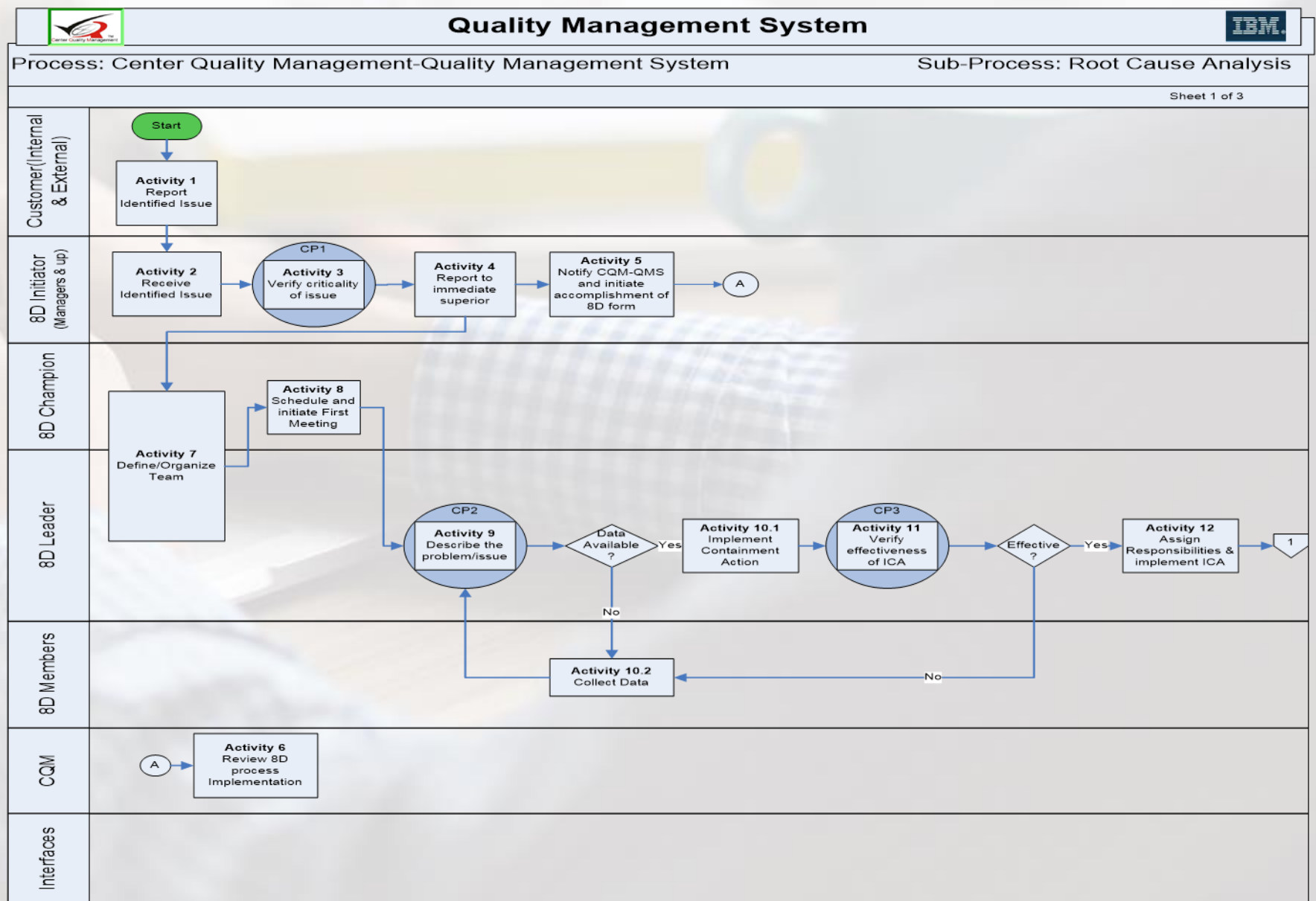


QMS and Internal Business Controls collaboration



Document Control System

Root Cause Analysis System



Benefits of QMS and QMS Internal Audits

- Verifies conformity to requirements
- Increases awareness and understanding
- Provides a measurement of effectiveness of the system to management
- Reduces risk of system failure
- Identifies improvement opportunities
- Precipitates the corrective action cycle
- Precipitates the preventive action cycle

A person's hands are shown typing on a silver laptop. The laptop screen displays a webpage with text and a sidebar. In the background, there is a wooden desk with a white coffee cup, a stack of books, and a decorative object. The scene is softly lit, creating a warm and professional atmosphere.

THANK YOU