



ISO 9001:2015 Quality Management System Awareness Training Course

(Q202.15 EH)

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Suggestions 建議

- Please turn communication devices to vibrating mode and avoid using it
請把通訊設備調到振動模式並避免使用
- Observe group rules
注意分組規則
- Emergency arrangement (safety exits etc)
緊急事故安排 (安全門等等)
- Local arrangements (hours, lunch, breaks)
本地安排 (時間, 午餐, 小息)
- Sit back and enjoy your session
放鬆並享受你的課程

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HKV

- Promote PDCA to organizations
- Deliver improvement based certification & training services
- Accredited by HKAS in 2003
- ISO 9001, ISO 14001, OHSAS 18001, ISO 22000, ISO 27001, ISO 50001 lead auditor courses approved by IRCA
- Macau office in 2005
- Vietnam office in 2008
- UK office in 2012
- A presence in 15 countries



Statue of Veritas
Supreme Court of Canada

In Roman mythology, **Veritas**, meaning truth, was the goddess of **truth**

Learning objectives 學習目標

- Describe the underlying principles of a QMS and understand the 7 QMP
描述品質管理系統的原則和理解7個品質管理原則
- Understand the key elements of ISO 9001
理解 ISO 9001 的主要內容

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Learning process 學習流程

- Powerpoint presentation
幻影片講授
- Group activities
分組活動
- Case study
案例研究
- Quiz
小測

Students are advised to take notes !
建議記筆記 !!

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SESSIONS

1 7 QUALITY MANAGEMENT PRINCIPLES	
2 ISO 9000 DEFINITIONS	
3 ISO 9001 REQUIREMENTS	
4 CASE STUDIES	

6

SESSION 1 8 QM PRINCIPLES



1.1 QUALITY BASICS

1.2 7 QM PRINCIPLES

7

富山驗房疑錯交遺體供火化



配錯藥事件死者增至3人

【本報記者王國強報導】富山醫院（Fukushima Hospital）日前發生一起嚴重的醫療事故，一名患者在接受手術後，因被錯誤地給予了含有砒霜的藥物，導致死亡。這是該醫院自今年年初以來發生的第三起類似事件。醫院方面表示，他們正在對事故進行調查，並對相關人員進行了處分。目前，已有兩名患者因類似原因死亡，第三名患者目前正在接受治療。醫院方面表示，他們將採取措施，防止類似事件再次發生。

ANOTHER BABY BLUNDER

【本報記者王國強報導】富山醫院（Fukushima Hospital）日前發生一起嚴重的醫療事故，一名患者在接受手術後，因被錯誤地給予了含有砒霜的藥物，導致死亡。這是該醫院自今年年初以來發生的第三起類似事件。醫院方面表示，他們正在對事故進行調查，並對相關人員進行了處分。目前，已有兩名患者因類似原因死亡，第三名患者目前正在接受治療。醫院方面表示，他們將採取措施，防止類似事件再次發生。

Quality evolution 品質演進

- Moving assembly line
移動裝配線
- Efficient & effective
有效率和有效
- Use of 'easily' trained labour
使用一般工人
- Ownership of quality began to lost
品質的責任開始模糊
- Inspection started
檢驗開始



Quality by detection 檢定技術

Inspection 檢驗	Quality control 品質控制
<ul style="list-style-type: none">• Sorting 分類• Grading 分級• Correction 改正	<ul style="list-style-type: none">• Procedures 程序• Basic planning 基本的策劃• AQL sampling 取樣

Quality by prevention 預防技術

Quality assurance 品質保證	Quality management 品質管理
<ul style="list-style-type: none">• Quality system 品質系統• SPC 統計流程控制• Quality planning 品質策劃	<ul style="list-style-type: none">• Customers 顧客• Policy 政策• Suppliers 供應商• Process 流程• Performance 業績• People 人員

Prevention vs Detection

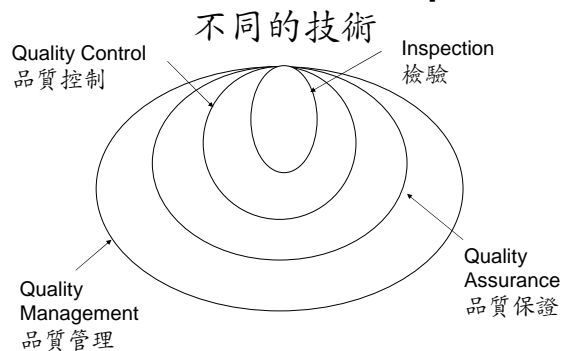
預防 對 檢定

Objective is to build in confidence,
so as to eliminate

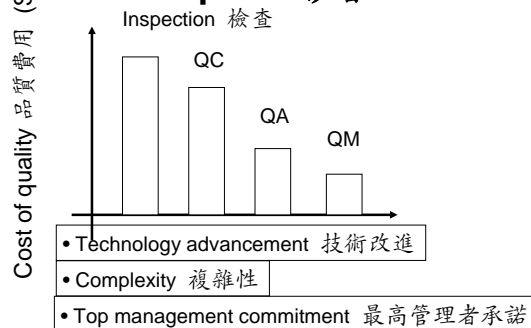
INSPECTION

目的是建立信心, 以避免檢查

The different techniques



And impact 影響...



GROUP EXERCISE



“What happened ?”

Objective(s)	Time
Given the case study (Q581), discuss/debate within your group what could have happened, and what should be done internally as a follow up. State any assumptions. Prepare output on a flip chart and have a spokesperson to present.	20 min.

SESSION 1

7 QM PRINCIPLES



1.1 QUALITY BASICS

1.2 7 QM PRINCIPLES

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7 Quality management principles

7個品質管理原則

- Customer focus 以顧客為重心
- Leadership 領導
- Engagement of people 全員投入
- Process approach 流程方法
- Improvement 改進
- Evidence based decision making
以證據為依歸的決策方法
- Relationship management
關係管理

QMP 2 Leadership 領導

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

各級領導者確立一致的宗旨及方向，並創造條件使員工充分投入以實現組織的品質目標。



QMP 7 Relationship Management

關係管理

For sustained success, organizations manage their relationships with interested parties, such as suppliers.



組織為達致持續成功，管理與相關方(如供應商)的關係。

QMP 6 Evidence-based Decision Making

以證據為依歸的決策方法

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.



按數據和信息的分析和評估所作的決定更能產生預期的成果。

QMP 1 Customer focus

以顧客為重心

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.



品質管理的首要重點是滿足顧客的要求，並爭取超越顧客期望。

QMP 3 Engagement of people

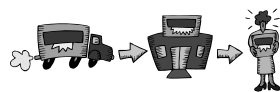
全員投入

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.

組織中具備能力，獲授權和投入的各級員工是提昇組織創造和實現價值能力的要素。



QMP 4 Process Approach 流程方法



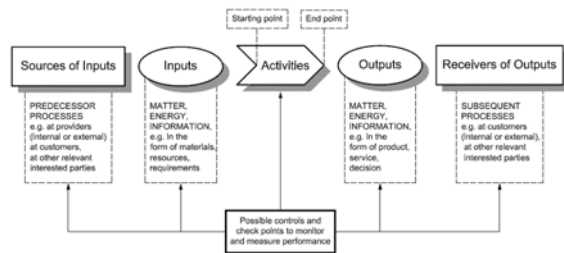
Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

當活動以相互關連的過程來理解和管理，使其功能上成為連貫的系統，便可更有效和有效率地實現一致和可預期的成果。

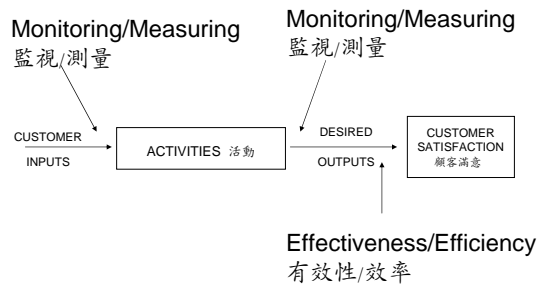
Process 流程

- Set of interrelated or interacting activities which transforms inputs into outputs
把輸入轉化成輸出的相互關係和相互作用的活動
- Outputs from one process are typically inputs into other processes
一個流程的輸出是另一流程的輸入
- Objective is to ADD VALUE 目標是增值
- Product is the result of process
產品是流程的結果

Process model 流程模型



Process model 流程模型



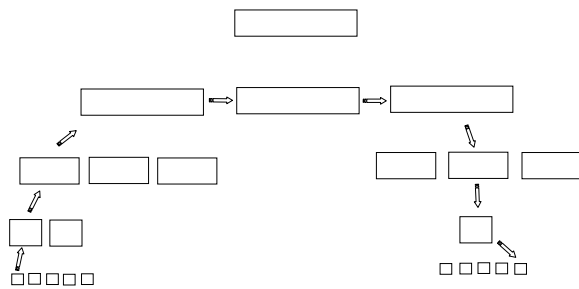
Managing processes 管理流程

- Start with process objectives
從流程目標開始
- Establish input, infrastructure, control requirements
確立輸入，基礎設施，控制要求
- Define competence/ownership
確定能力
- Monitor, measure and improve
監視，測量和改進

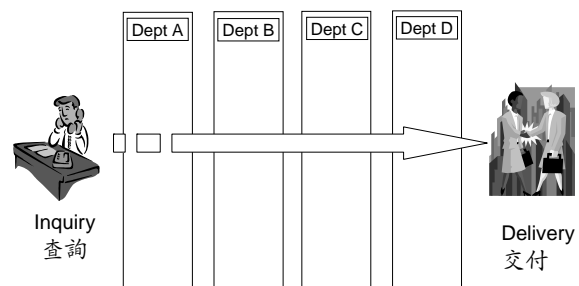
Benefits 好處

- Integration and alignment of linked activities to achieve planned results
整合協調相關的活動,實現策劃的結果
- Platform for continual improvement
持續改進的平台
- Encouragement of people involvement and clarification of responsibilities
澄清職責,鼓勵參與
- Transparency of operation 營運透明化
- Provision of confidence to customers
提升顧客的信心

Typical Old Organization 典型架構

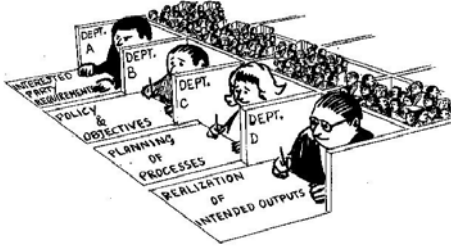


New Focus on Process 流程為主

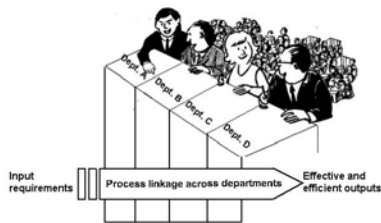


Traditional hierarchy are managed vertically
(low visibility of customer in some areas)

傳統垂直管理模式
(在某些區域顧客能見度較低)



Processes managed as a system
流程以系統方式管理



QMP 5 Improvement 改進

Successful organizations have an ongoing focus on improvement.

成功的組織不斷地
以改進為重心。



Deming PDCA cycle 戴明循環

Study and learn

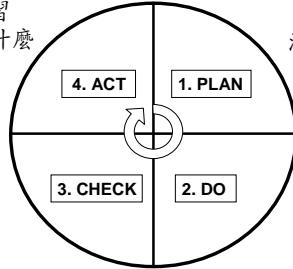
What can we predict ?

研究並且學習
我們能預言什麼

Decide purpose and
changes?

決定目的和變化

觀察影響
Observe
effects



小規模改變
Small scale
change

SESSION 2

ISO 9000 DEFINITIONS



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What is ISO ? 什麼是 ISO ?

What is ISO 9000 family ?

什麼是ISO 9000系列 ?



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ISO management system standards

ISO 管理系統標準

New Structure 新架構 : Annex 附件SL

- Defines the framework for a generic management system
制訂通用管理系統標準的框架
- All new ISO management system standards (MSS) has to follow
所有新的ISO管理系統標準（MSS）必須跟隨

Annex 附件 SL

Context of the organization

組織的景況 (3.2.2)

Combination of internal and external issues that can have an effect on an organization's (3.2.1) approach to developing and achieving its objectives (3.7.1)

可影響組織（3.2.1）前景和實現其目標（3.7.1）的內外因素的組合

Risk 風險 (ISO 9000:2015 3.7.9)

effect of uncertainty

不確定性的影響

GROUP EXERCISE

“Context and Risks”



Objective(s)	Time
Discuss the “context” and risks of the Macau U. Identify the internal and external issues.	20 min.
Prepare output on a flip chart and have a spokesperson to present.	

Quality 品質 (ISO 9000:2015 3.6.2)

degree to which a set of inherent characteristics (3.10.1) of an object (3.6.1) fulfils requirements (3.6.4)

一件物件(3.6.1)的固有特性(3.5.1) 滿足要求(3.1.2)的程度

Requirement 要求 (ISO 9000:2015 3.6.4)

Need or expectation that is stated, generally implied or obligatory

明示, 通常隱含或必須履行的需求或期望

‘Generally implied’ means it is common practice
通常隱含表示慣例或一般做法

Specified requirement is one which is stated
規定要求是經明示的要求

Customer 顧客 (ISO 9000:2015 3.2.4)

person or organization (3.2.1) that could or does receive a product (3.7.6) or a service (3.7.7) that is intended for or required by this person or organization

接收或可能接收有意提供或要求產品（3.7.6）或服務（3.7.7）的個人或組織（3.2.1）。

Customer 顧客 (ISO 9000:2015 3.2.4)

- Can be internal or external
它可能是內在組織，或外部的
- Could be consumer, end-user, retailer, beneficiary, purchaser, receiver
可能是消費者，最終用戶，零售商，受益者，買家，接收者.....
- Could be more than 1
可能超過 1

Interested Party 利益相關方

(ISO 9000:2015 3.2.3)

person or organization (3.2.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

可以影響，受到影響，或感覺會受到影響決策或活動的個人或組織（3.2.1）。

Product 產品 (ISO 9000:2015 3.7.6)

output (3.7.5) of an organization (3.2.1) that can be produced without any transaction taking place between the organization and the customer (3.2.4)

組織 (3.2.1) 的輸出 (3.7.5)，可以在組織與顧客 (3.2.4) 之間沒有發生任何交易中產生

Product 產品 (ISO 9000:2015 3.7.6)

- Generally tangible
通常是有形
- Include Hardware , Processed Materials, Software
包括硬件, 流程性材料和軟件

Service 服務 (ISO 9000:2015 3.7.7)

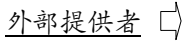
output (3.7.5) of an organization (3.2.1) with at least one activity necessarily performed between the organization and the customer (3.2.4)

組織 (3.2.1) 的輸出 (3.7.5)，至少在組織與顧客 (3.2.4) 之間必要進行一項活動

(ISO 9000:2015 3.7.7)

- 通常是非物质

供應鏈



組織

顧客

External Provider

Organization

Customer

(3.2.6)

(3.2.1)

(3.2.4)

產品和服務

Product and Service

(3.7.6)

$$(3.7.7)$$

What are the products and service in a school? 學校的產品和服務是什麼？

Who are interested parties 利益相關方是誰?

“Product, customers and requirements”



Objective(s)	Time
Based on a certain operating unit, identify the product(s), different customer groups and their requirements (stated, generally implied and obligatory) Prepare output on a flip chart and have a spokesperson to present.	20 min.

Top Management 最高管理層

(3.1.1)

Person or group of people who directs and controls an organization (3.2.1) at the highest level

在最高層指揮和控制組織（3.2.1）的個人或團隊

Quality policy 品質政策

(3.5.9)

Intentions and direction of an organization (3.2.1) as formally expressed by its top management (3.1.1) related to quality

由組織（3.2.1）的最高管理者（3.1.1）正式發佈的品質宗旨和方向

Competence 能力

(3.10.4)

Ability to apply knowledge and skills to achieve intended results

可以運用知識和技能達到預期效果的本領

ISO 9001:2015 focused on the competence of individual rather than training (records)
ISO 9001:2015 強調個人能力而不是培訓（記錄）

Process and Procedure 流程和程序

Process 流程 (3.4.1)

Set of interrelated or interacting activities that use inputs to deliver an intended result

使用輸入以達致預期結果的相互關聯或相互作用的活動

Procedure 程序 (3.4.5)

Specified way to carry out an activity or a process
進行一項活動或者一個流程指定模式

(Procedures may or may not be documented)

(程序可用或不用文件化)

Infrastructure 基礎設施 (3.5.2)

<organization> system (3.5.1) of facilities, equipment and services (3.7.7) needed for the operation of an organization (3.2.1)

一個組織 (3.2.1) 運作所必須的設施, 設備和服務 (3.7.7) 的<組織>系統 (3.5.1)

Work environment 工作環境 (3.5.5) (Process environment)

Set of conditions under which work is performed

工作時所處的一組條件

Conditions include physical and environmental factors

條件包括物理的和環境因素

Documented information

文件化信息 (3.8.6)

Information (3.8.2) required to be controlled and maintained by an organization (3.2.1) and the medium on which it is contained

組織 (3.2.1) 需要控制和維護的信息 (3.8.2) 及其承載的媒體

Maintain documented Information 保持文件化信息

Retain documented Information 保留文件化信息

Property belongings to customers or external providers

(ISO 9001 8.5.3)

顧客或外部提供者財產

Include materials, components, tools and equipment, premises, intellectual property and personal data

包括材料，零部件，工具，設備，場地，知識產權和個人資料

Corrective Action 矯正措施

(ISO 9000:2015 3.12.2)

Action to eliminate the cause of a detected nonconformity (3.6.9) and to prevent recurrence

消除已發現不符合 (3.6.9) 的原因以防止再發生所採取的措施

Example 例

The removal of the cause of infection of a SARS infected staff. (e.g. Inadequate protection)
清除非典感染的源頭 (不足的防護)

SESSION 3

ISO 9001 REQUIREMENTS

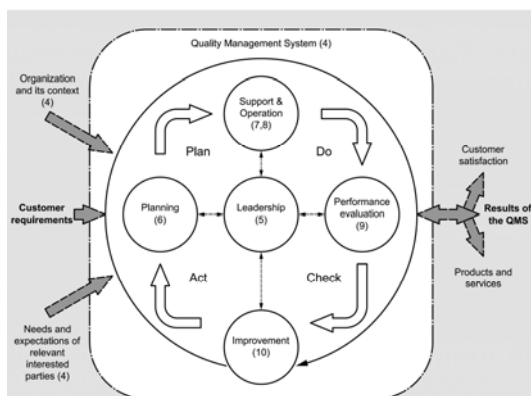


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Purpose of ISO 9001 目的

Specifies requirements for organization to
指定組織的要求

- Demonstrate its ability to consistently provide product that meets applicable requirements
證明它一貫提供滿足要求的產品的能力
- Enhance customer satisfaction thru system
透過系統提升顧客滿意度
 - processes for improvement & conformity assurance
改進和符合保證的流程
- Prevent nonconformity
防止不符合



Benefits of implementation

實施的好處

- Management platform 管理平台
- Facilitation of business and trade 促進貿易
- Stakeholder/customer confidence 提升顧客信心
- Staff relations 職員關係
- Financial 財政

Above derived without certification! 不需要認證!

Contents 目錄

1. Scope 範圍
2. Normative references 引用標準
3. Terms and definitions 述語和定義
4. Context of the organization 組織的景況
5. Leadership 領導
6. Planning for the QMS 品質管理系統的策劃
7. Support 支持
8. Operation 營運
9. Performance evaluation 績效評價
10. Improvement 改進

ISO 9001:2015 Requirements 要求

For ISO 9001 documented information requirements, please refer to Q823
有關 ISO 9001 文件化程序和記錄要求, 請參閱 Q823

SESSION 4
CASE STUDIES



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Thank You

Hope that you have enjoyed the course !!

Tell your friend if you like it,
Tell us what you don't like !
