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ISO/DIS9001:2008
VS
ISO9001:2000

Speaker: Ir. Dr. Aaron TONG

Date:2008-08-01

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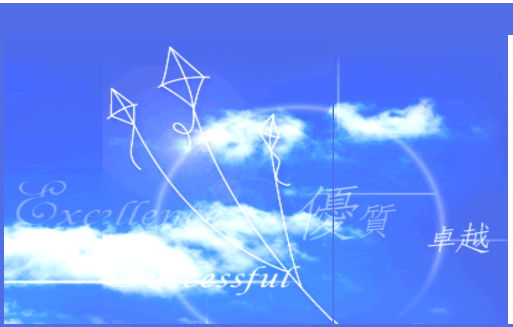
Outline

- Background Information of ISO/DIS 9001 : 2008
- Main Changes of 2008 Edition
- What we should do?
- Q & A Section



Speaker Introduction

- **Ir. Dr. Aaron TONG**
  - Observer of the **ISO/TC-176 Committee**
  - 1 of the 3 fellows of ASQ in Great China
  - Helped more than 60% of HKSAR Government Departments obtained various Mgt. Sys. Certificates

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ISO/TC-176

- **Responsible for the review and update of ISO 9001**
  - 80 P-Members (in countries)
  - 21 O-Members, including *HONG KONG*
  - 11 Internal Liaison Organizations
  - Other External Liaison Organizations

- **High level of participation of China**

■ one of the Participating Member

■ Mr. Tienan Li of China, the Vice Chairman of TC-176

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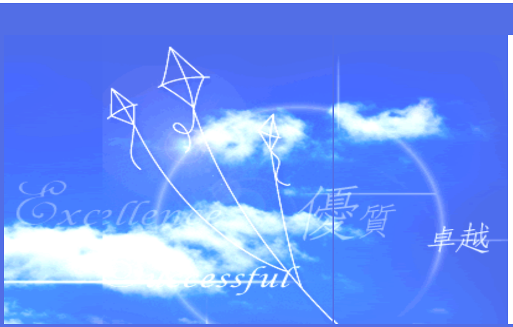
History of ISO 9001…

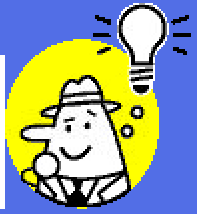
- **First Published in 1987**
- **Edited in 1994 (2nd edition) and 2000 (3rd edition)**
- **One million ISO 9001 Certificates have been issued in 170 Countries**
- **Including Private & Public sectors and Manufacturing & Services**



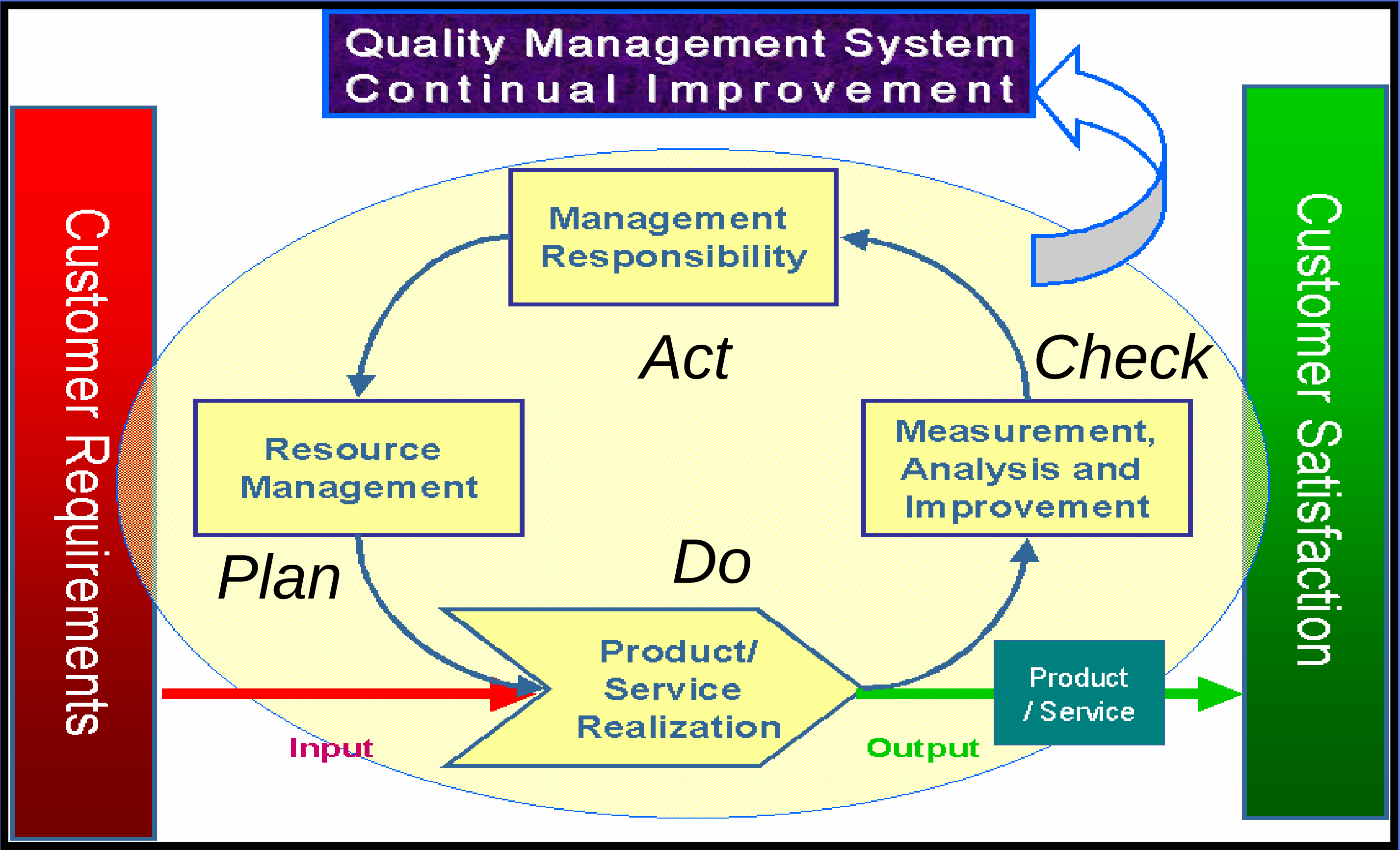
History of ISO 9001…

- **The Third Edition published in 2000**
  - Representing a Thorough Revision
  - Including New Requirements
  - Sharpening Customer Focus
  - Reflecting Developments in Quality Management & Experience Gained
  - Adopt Process Approach

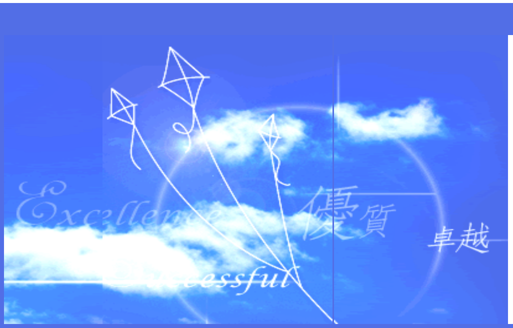
Product = Service



History of ISO 9001…


Quality Management System
Continual Improvement
Customer Requirements
Management Responsibility
Act
Check
Resource Management
Measurement, Analysis and Improvement
Plan
Do
Product/ Service Realization
Input
Output
Product / Service
Customer Satisfaction

Model of a Process-based QMS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Main Points of ISO 9001 : 2008

● Date of Release

- ■ October or November of 2008

  (Source : News from ISO Website)

- ■ November or December of 2008

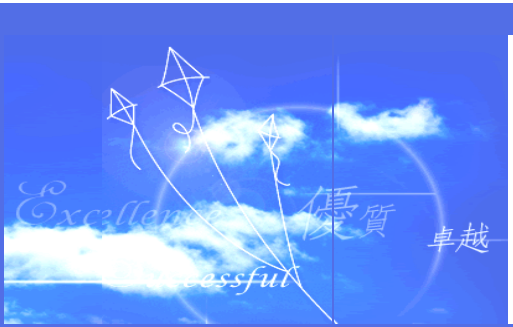
  (Source : ISO / TC 176 Meeting Minutes)

Changes in Clauses

- **3 Terms and definitions**
  - ~~The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:~~

    ~~supplier → organization → customer~~

    ~~The term “organization” replaces the term “supplier” used in ISO9001:1994 and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the tem “subcontractor”.~~



Changes in Clauses

● 4.1 General Requirements

a) ~~Identify~~ determine the processes needed for the quality management system and their application throughout the organization

e) monitor, measure (where applicable) and analyse these processes, and

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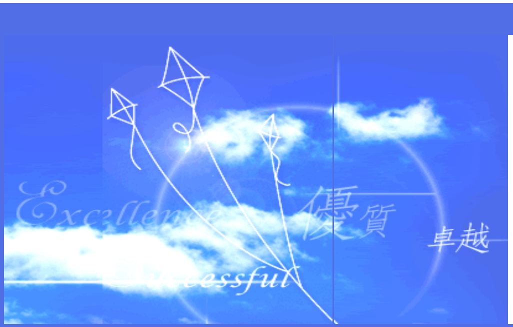
Changes in Clauses(4.1)

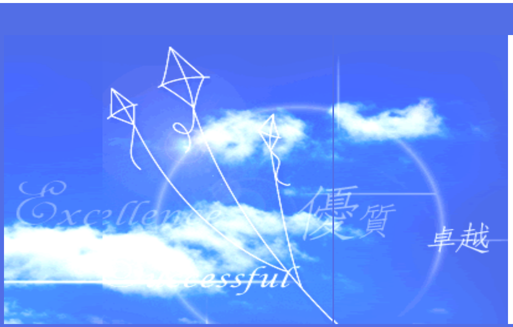
When an organization chooses ~~with~~ to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. ~~Control of such outsourced processes shall be identified within the quality management system~~ The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.



Changes in Clauses(4.1)

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement , analysis and improvement.

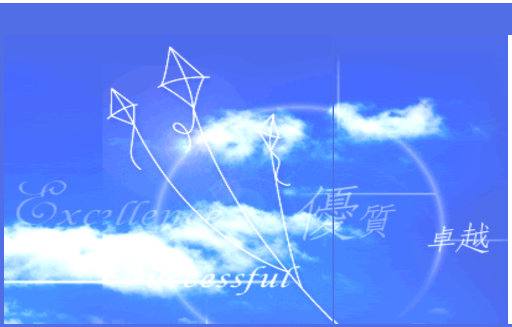
NOTE 2 An outsourced process is identified as one being needed for the organization's quality management system but chosen to be performed by a party external to the organization.



Changes in Clauses(4.1)

- **NOTE 3 The type and nature of control to be applied to the outsourced process may be influenced by factors such as:**
  - a) the potential impact of the outsourced process on the organization’s capability to provide product that conforms to requirements;
  - b) the extent to which the control for the process is shared;
  - c) The capability of achieving the necessary control through the application of clause 7.4.

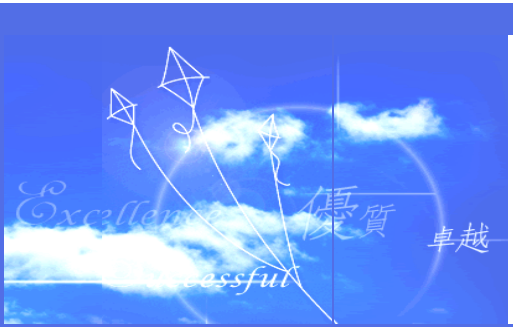
Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements.



Changes in Clauses

● 4.2.1 General

- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.
- Note1 A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be recovered by more than one document.



Changes in Clauses

- ## 4.2.3 Control of Documents
  - f) to ensure that documents of external origin **determined by the organization to be necessary for the planning and operation of the quality management system** are identified and their distribution controlled, and…

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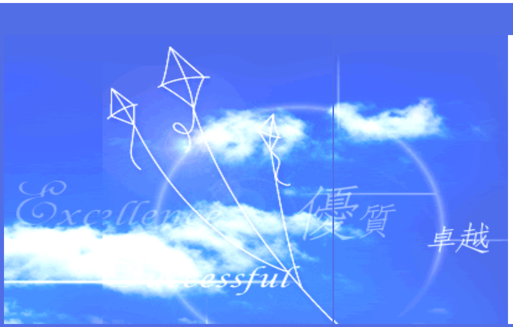
Changes in Clauses

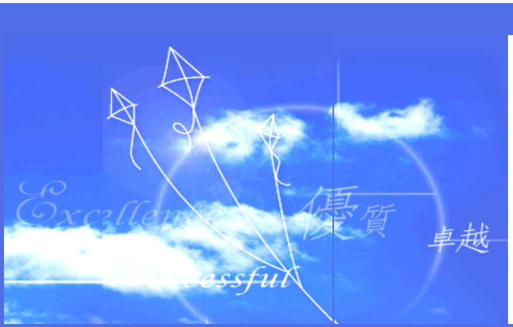
5.2.2 Management representative

- Top management shall appoint a member of the organizations’ management who, irrespective of other responsibilities, shall have responsibility and authority that includes



Changes in Clauses

- **6.2.1 General**
  - NOTE Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.



Changes in Clauses

- **6.2.2 Competence, training and awareness**
  - a) determine the necessary competence for personnel performing work affecting conformity to product ~~quality~~ requirements.
  - b) where applicable, provide training or take other actions to achieve the necessary competence
  - c) ~~evaluate the effectiveness of the action taken~~

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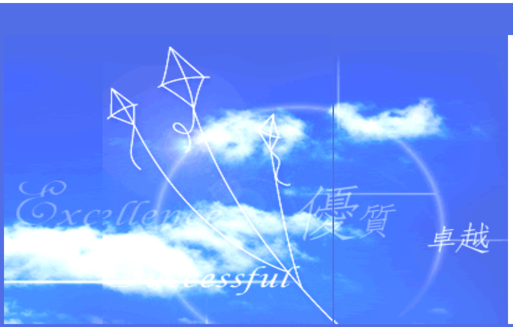
Changes in Clauses

- **6.2.2 Competence, training and awareness**
  - c) ~~evaluate the effectiveness of the action taken~~ ~~ensure~~ that the necessary competence has been achieved

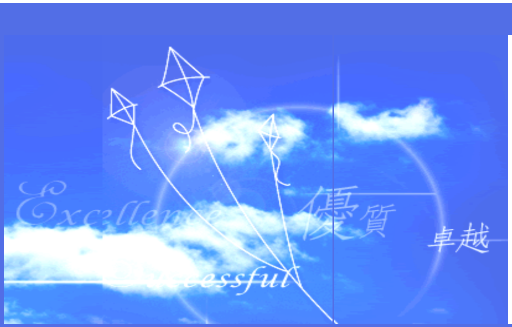
- **6.3 Infrastructure**
  - c) supporting services (such as transport, communication or information system)



Changes in Clauses

6.4 Work environment

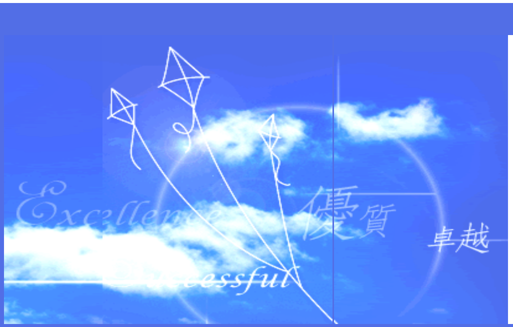
- NOTE The Term “work environment” related to conditions under work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).



Changes in Clauses

● 7.2.1 Determination of requirements related to the product

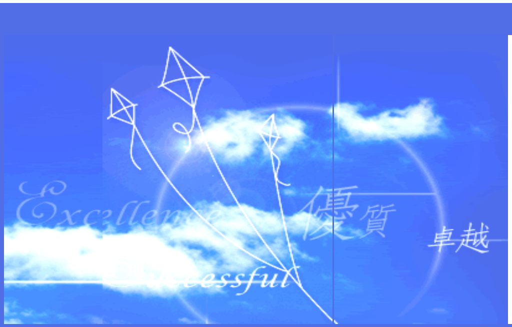
- NOTE Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.



Changes in Clauses

- **7.3.3 Design and development outputs**
  - NOTE Information for production and service provision may include details for the preservation of product.

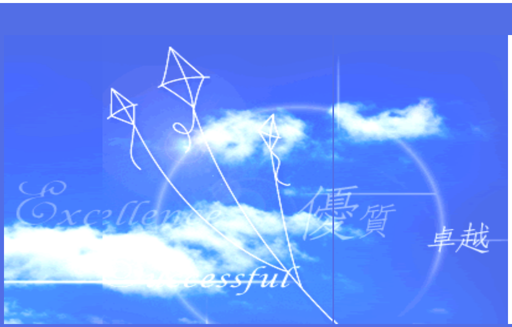
- **7.5.2 Validation of processes for production and service provision**
  - ….subsequent monitoring or measurement and as a consequence, ~~This includes any processes where~~ deficiencies become apparent only after the…



Changes in Clauses

- **7.5.4 Customer property**
  - NOTE Customer property can include intellectual property and personal data.

- **7.6 Control of monitoring and measuring equipment**
  - ~~NOTE See ISO 10012-1 and ISO 10012-2 for guidance~~. Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.



Changes in Clauses

- **8.2.1 Customer Satisfaction**

  NOTE Monitoring customer perception may include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.

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Changes in Clauses

8.2.2 Internal audit

- A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
- Records of the audits and their results shall be maintained (see 4.2.4).
- NOTE See ~~ISO 10011-1, ISO 10011-2 and ISO 10011-3~~ ISO 19011 for guidance.

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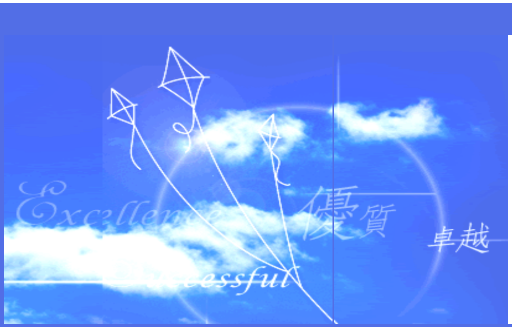
Changes in Clauses

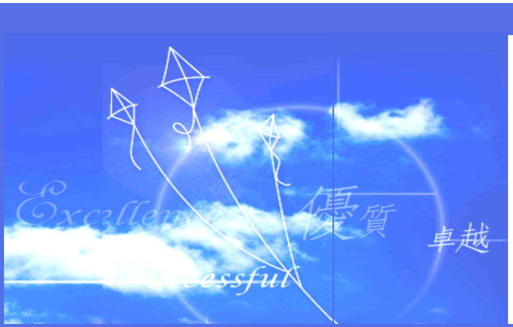
- **8.2.3 Monitoring and measurement of processes**
  - The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, ~~to ensure conformity of the product.~~



Changes in Clauses

- **8.2.3 Monitoring and measurement of processes**

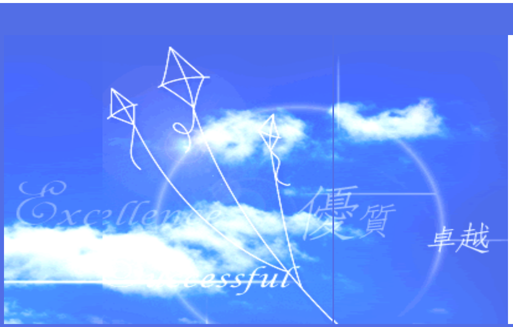
NOTE when determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.



Changes in Clauses

- **8.3 Control of Nonconforming product**

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. ~~The controls related responsibility and authorities dealing with nonconforming product shall be defined in a document procedure.~~ A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

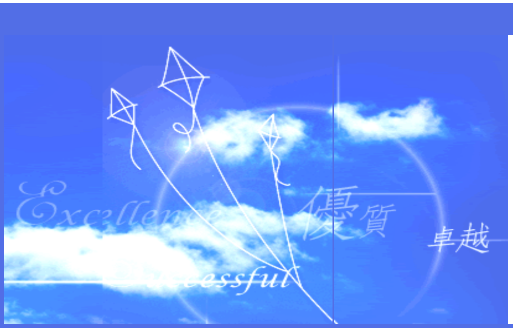


Changes in Clauses(8.3)

When practicable, the organization shall deal with nonconforming product by one or more of the following ways:

d) by taking action appropriate to the effects, or potential effects, of the nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.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What's Next in Quality Management?

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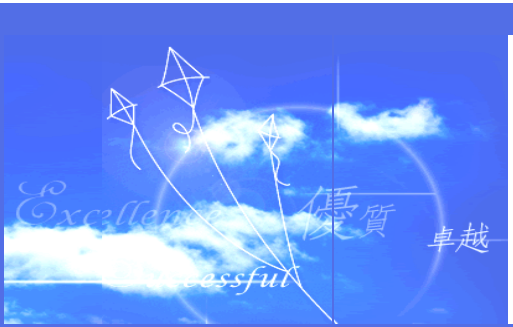
What’s Next in Qu Mgt?

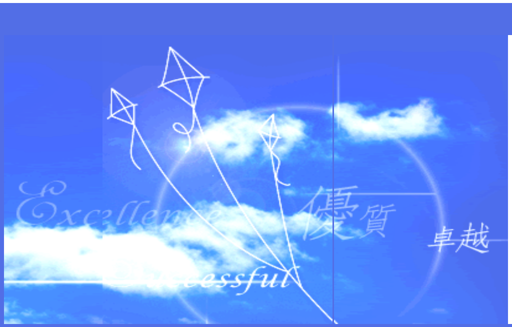
- **ISO/TC 176 arranged two workshops:**
  - Work on time, speed and agility
  - Deal with innovation

as part of quality management



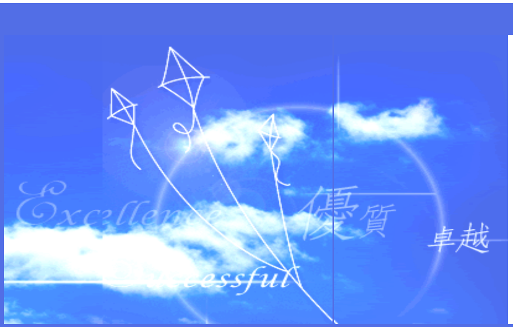
What we should do?

- **For current ISO 9001:2000**
  - Review current system and practices
  - Change in documentations if necessary
    - Manuals
    - Procedures, etc
  - Streamline the workflow if necessary
  - Attend training to better understand the new version
  - Seek advices from (current) consulting parties



What we should do?

- **Main Points of ISO 9001 : 2008**
  - A Fine-Tuning
  - No *NEW* Requirements
  - No Specific Reassessment for Certification
  - Same Intention as 2000 Version
    - Customer Satisfaction
    - Regulatory Compliance
    - Continual Improvement



What we should do?

- **Digest and appreciate the changes on ISO 9001:2008.**
- **Work with your consultants and certificate bodies to arrange the smooth upgrade.**
- **Any changes must be:**
  - Add value to your customers and organizations, no need to please the certification bodies and/or auditors.

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Contact of Ir. Dr. TONG

- Ir Dr Aaron TONG
- TQM CONSULTANTS CO. LIMITED
- Tel: 2569 2883
- E-mail: awktong@tqm.com.hk

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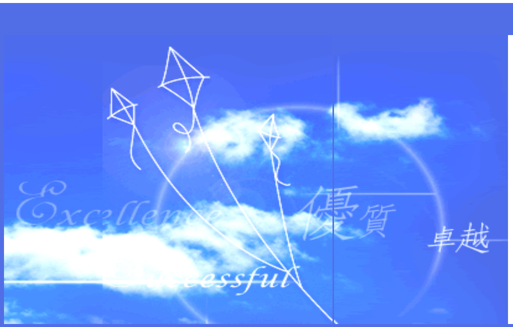
ISO 9001:2008 Quality Management System

BENEFITS OF IMPLEMENTING ISO 9000

OUR DELIGHTED CLIENTS



- **Special Thanks to our present clients:**

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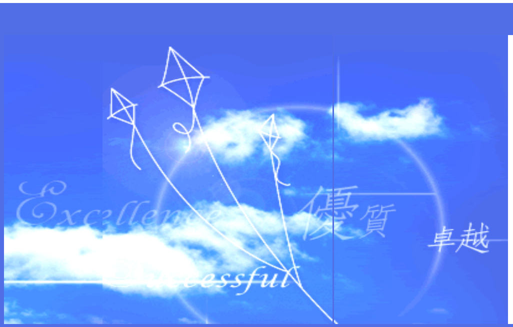
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Q & A