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Practical Tips to PASS ISO 9001:2008 Audit

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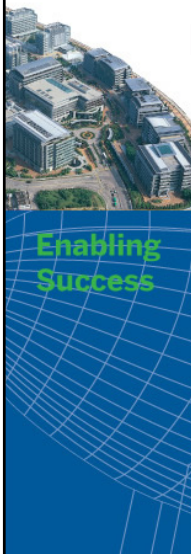
Agenda

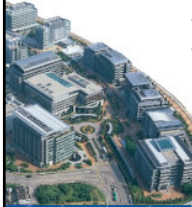
Part 1.

- Experience sharing focus on the changes between ISO 9001:2000 and ISO 9001:2008
- Comparison with other standards

Part 2.

- Perspective: Value-added through Quality





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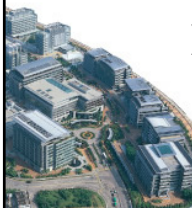
Main change & our solution

➤ 4.1 General requirements

- Para 4: The type and extent of control to be applied to these **outsourced processes** shall be defined.
- Note 3: Ensuring control over outsourced process

➤ HKSTP Actions:

- Followed ISO 17025 and HOKLAS policy requirements



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Other requirements

➤ ISO/IEC 17025:2005

- 4.5 Subcontracting of tests and calibrations

4.5.H HOKLAS Policy on Sub-contracting of tests and calibrations

Laboratories shall document their policy and procedures for sub-contracting in the quality manual or related documents. For accredited tests and calibration, the sub-contracted laboratory shall be accredited under HOKLAS, or be a laboratory accredited under a scheme with which HOKLAS has a recognition arrangement (MRA), for the relevant tests or calibrations. Relevant regulations governing the subcontracting of work and reporting of results from subcontractors are given in HKAS 002. The HOKLAS policy on reporting results from subcontractors for which a laboratory is not responsible as allowed in clause 4.5.3 is detailed in 5.10.H(g).

HKAS will grant accreditation to a laboratory only for those activities which the laboratory itself is competent to carry out and which it normally performs by itself

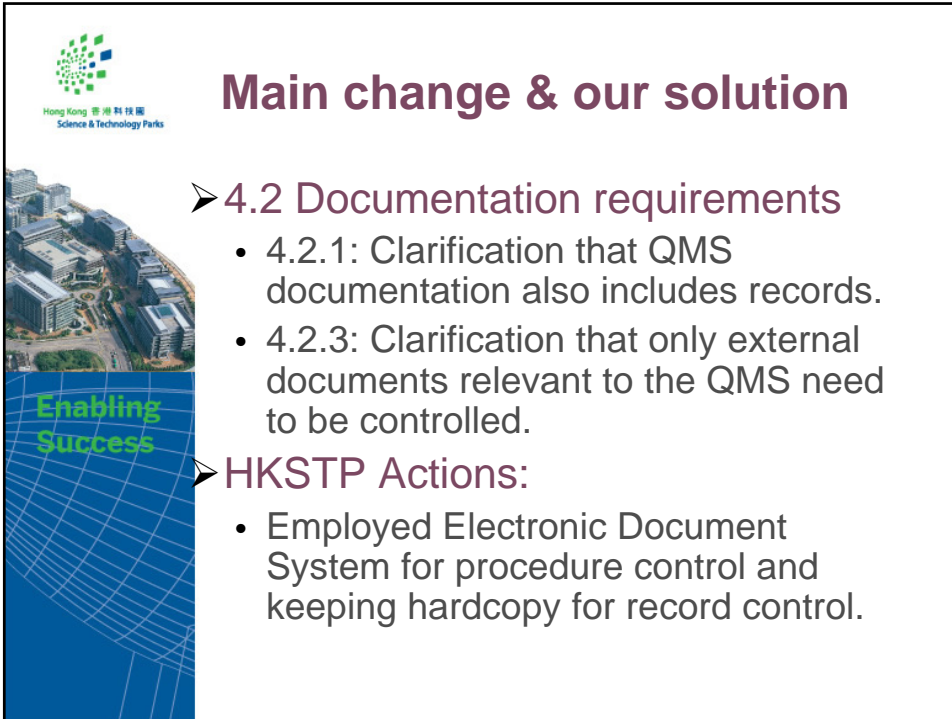
Main change & our solution

➤ 4.2 Documentation requirements

- 4.2.1: Clarification that QMS documentation also includes records.
- 4.2.3: Clarification that only external documents relevant to the QMS need to be controlled.

➤ HKSTP Actions:

- Employed Electronic Document System for procedure control and keeping hardcopy for record control.



Other requirements

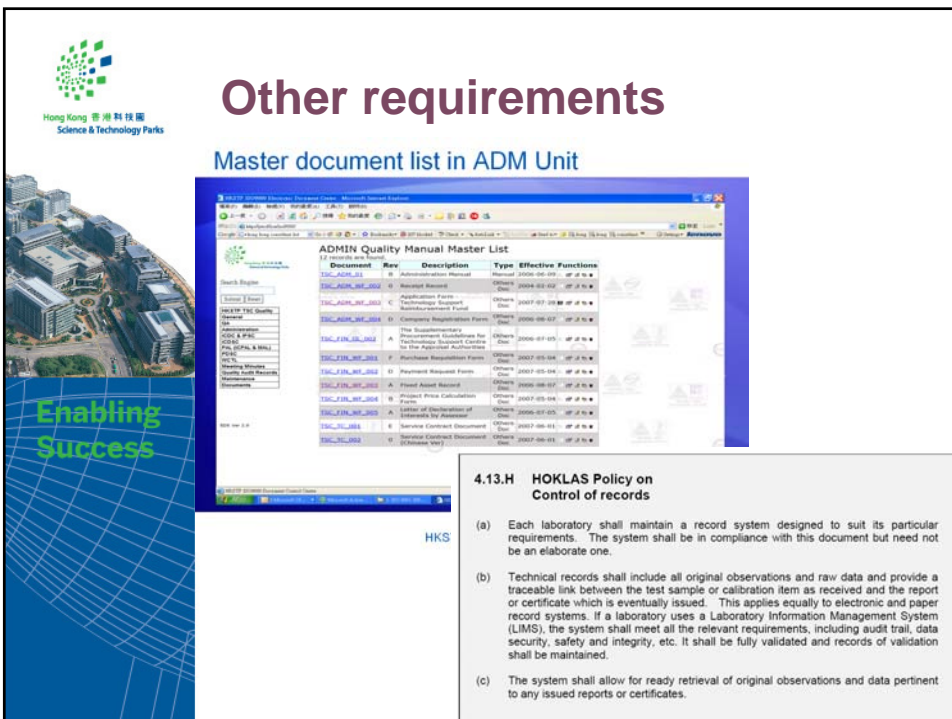
Master document list in ADM Unit

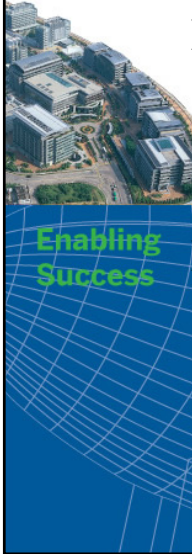


Document No.	Description	Type	Effective	Functions
TSC_ADM_01	Administrative Manual	Manual	2004-05-01	...
TSC_ADM_02	Record Record	Others	2004-05-01	...
TSC_ADM_03	Application Form	Form	2007-07-01	...
TSC_ADM_04	Technology Request	Form	2007-07-01	...
TSC_ADM_05	Infrastructure Form	Form	2006-08-01	...
TSC_ADM_06	Procurement Specification for Technology Request	Others	2006-07-01	...
TSC_ADM_07	Procurement Specification for Infrastructure Request	Others	2007-05-04	...
TSC_ADM_08	Procurement Specification for Procurement Request	Others	2007-05-04	...
TSC_ADM_09	Procurement Request Form	Form	2006-08-01	...
TSC_ADM_10	Invoice Price Calculation	Form	2007-05-04	...
TSC_ADM_11	Contract of Equipment	Others	2006-07-01	...
TSC_ADM_12	Supplier Contract Document	Form	2006-08-01	...
TSC_ADM_13	Supplier Contract Document (Scheme ver)	Form	2007-06-01	...

4.13.H HOKLAS Policy on Control of records

- Each laboratory shall maintain a record system designed to suit its particular requirements. The system shall be in compliance with this document but need not be an elaborate one.
- Technical records shall include all original observations and raw data and provide a traceable link between the test sample or calibration item as received and the report or certificate which is eventually issued. This applies equally to electronic and paper record systems. If a laboratory uses a Laboratory Information Management System (LIMS), the system shall meet all the relevant requirements, including audit trail, data security, safety and integrity, etc. It shall be fully validated and records of validation shall be maintained.
- The system shall allow for ready retrieval of original observations and data pertinent to any issued reports or certificates.





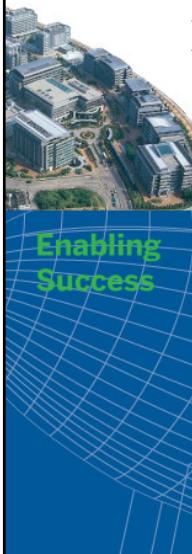
Main change & our solution

➤ 5.5.2 Manager representative

- MR must be a member of the organization's **own management**.

➤ HKSTP Actions:

- MR employed



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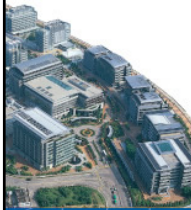
➤ 6.2.2 Competence, training and awareness

- b) where applicable, provide training or take other actions achieve the **necessary competence**

➤ HKSTP Actions:

- Provide different training for awareness, implementation and auditing including QMS, Lab safety, ISMS, etc.

International standard Comparison



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ISO 9001	ISO 14001	BS OHSAS 18001	ISO/IEC 27001	ISO/IEC 17025
6.2.2 Competence, awareness and training	4.2.2 Competence training and awareness	4.4.2 Competence, training and awareness	5.2.2 Training, awareness & competence A8.2.2 Info. Security awareness, education & training	5.2 Personnel
<ul style="list-style-type: none"> ● appropriate education, training, skills & experience 	<ul style="list-style-type: none"> ● appropriate education, training, or experience ● establish, implement & maintain a procedure 	<ul style="list-style-type: none"> ● appropriate education, training, or experience ● identify training needs (OH&S risks & MS) ● establish, implement & maintain a procedure 	<ul style="list-style-type: none"> ● education, training, skills, experience & qualifications (records) ● Implement training & awareness programmes ● Competent to perform the required tasks 	<ul style="list-style-type: none"> ● Competence of operating specific equipment, performing tests and/or calibrations, evaluating results and sign test report & calibration certificates. ● appropriate education, training, experience and/or DEMONSTRATED Skill
<ul style="list-style-type: none"> -Determine the necessary competence -Provide training -Evaluate the effectiveness -Awareness -Maintain appropriate record 	<ul style="list-style-type: none"> -Conformity with the environmental policy -Significant env. aspects -Roles & responsibilities -Potential consequences of departure 	<ul style="list-style-type: none"> -OH&S consequences -Roles & responsibilities -Requirement of OH&S MS (emergency preparedness & response requirement) -Training procedures in different level of responsibility, ability, language skills, literacy; and risk 	<ul style="list-style-type: none"> -Determining the necessary competencies in ISMS -Providing training -Evaluating the effectiveness -Maintaining records <p>In A8.2.2, including employees, contractors & third part users</p>	<ul style="list-style-type: none"> -policy & procedures for identifying training needs -The effectiveness of training actions taken shall be evaluated

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- 6.3 Infrastructure **(Audit – AFI)**
 - c) supporting services (such as transport, communication or **information systems**)
- 6.4 Work environment
 - Clarifies that this includes conditions under which work is performed.
- HKSTP Actions:
 - Achieved ISO 27001 in ICDC & IPSC and employed its spirit to other units.
 - Work environment in laboratories had tight requirement based on ISO 17025.



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Other requirements

A.10.6 Network security management

Objective: To ensure the protection of information in networks and the protection of the supporting infrastructure.

A.10.6.1	Network controls	<i>Control</i> Networks shall be adequately managed and controlled, in order to be protected from threats, and to maintain security for the systems and applications using the network, including information in transit.
A.10.6.2	Security of network services	<i>Control</i> Security features, service levels, and management requirements of all network services shall be identified and included in any network services agreement, whether these services are provided in-house or outsourced.

5.3 Accommodation and environmental conditions

5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

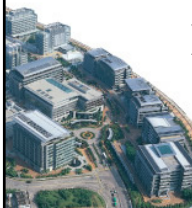
The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

5.3.3 There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

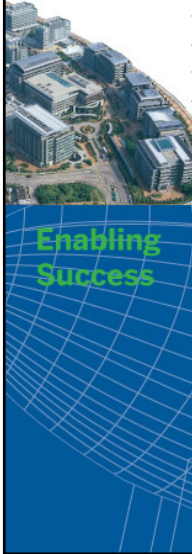
5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.



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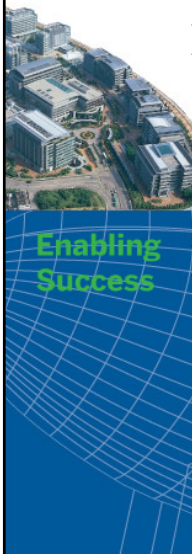
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- 7.5.3 Identification and traceability
 - Clarifies that **identification of product status** must be maintained throughout product realization
- HKSTP Actions:
 - Sample ID (traceability) was very important and followed HOKLAS requirement.



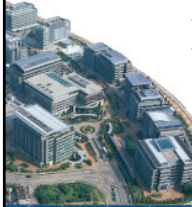
Other requirement

- **ISO 17025**
- 5.6 Measurement traceability
- **HOKLAS 003**
- 5.6.H HOKLAS Policy on Measurement traceability
- Very big chapter!!!



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- 7.5.4 Customer property
(Audit – AFI)
 - NOTE: Customer property can include intellectual property **and personal data.**
- **HKSTP Actions:**
 - Achieved ISO 27001 in ICDC & IPSC and employed its spirit to other units.
 - Followed HOKLAS requirement



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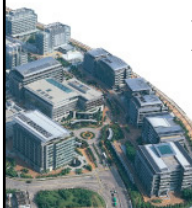
Other requirement

➤ ISO 27001: A.15.1 Compliance with legal requirements

A.15.1.4	Data protection and privacy of personal information	<p><i>Control</i></p> <p>Data protection and privacy shall be ensured as required in relevant legislation, regulations, and, if applicable, contractual clauses.</p>
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5.8.H HOKLAS Policy on Handling of test and calibration items

- (a) On receipt, a calibration or test item shall be registered into the laboratory records. The form of registration may vary. In most laboratories a sample or item register will be used, but in some cases, details of the samples or items may be written directly on worksheets or into workbooks. Certain information on the received sample or item is essential and such criteria are covered in section 4.13.2 on "Technical Records".
- (b) Where it is necessary to store samples or items after tests or calibrations, the laboratory shall ensure that appropriate storage facilities are available for avoiding deterioration, loss or damage. The suitability of such storage facilities will be covered in assessments.
- (c) The disposal procedure of tested samples and items shall be such that confidential information and proprietary rights of the customers are well protected in the process.



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➤ 7.6 Control of monitoring and measuring equipment

- NOTE: 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.

➤ HKSTP Actions:

- Follow ISO 17025 requirement for equipment application software

Other requirement

➤ ISO 17025:2005

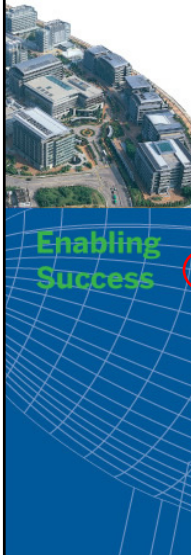
5.4.7 Control of data

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

- a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE Commercial off-the-shelf software (e.g. wordprocessing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).



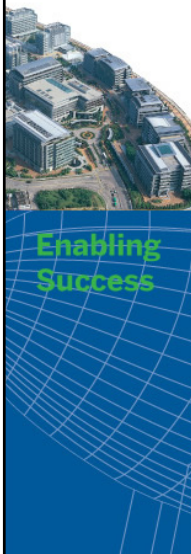
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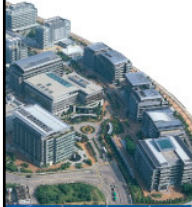
➤ 8.2.1 Customer Satisfaction

- NOTE: **Monitoring customer perception** can include obtaining input from sources such as customer satisfaction surveys, ... etc.

➤ HKSTP Actions:

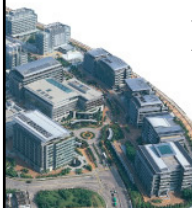
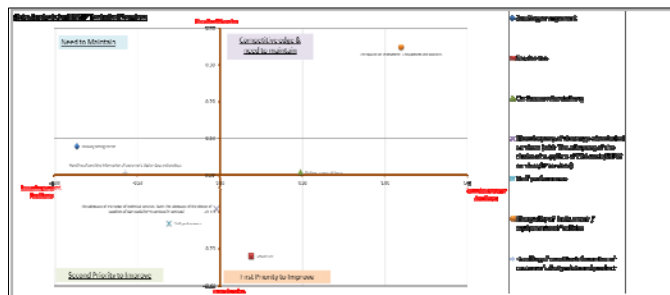
- Development Lab Service Questionnaire
- Development Tech Fans Club to communication with customer





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Other requirement



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➤ 8.2.2 Internal audit

- The standard now requires the area being audited to ensure that **any necessary corrections and corrective actions** are taken without undue delay.....

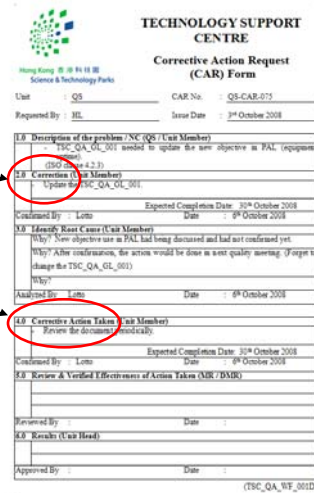
➤ HKSTP Actions:

- Our original CAR have been already separated Correction and Corrective Actions.

Other requirement

➤ HKSTP CAR

- Correction
- Corrective action



TECHNOLOGY SUPPORT CENTRE
Corrective Action Request (CAR) Form

Unit : QS CAR No. : QS-CAR-075
Requested By : HL Issue Date : 3rd October 2008

1.0 Description of the problem / NC (QC Unit Member)
TSC_QA_OC_001 needed to update the new objective in PAL (equipment) (ISO 9001 4.2.3)

1.1 Correction (Unit Member)
Update TSC_QA_OC_001

Guided By : Loto Expected Completion Date : 10th October 2008
Date : 0th October 2008

1.2 Corrective Action Taken (Unit Member)
Reverse the document

Guided By : Loto Expected Completion Date : 10th October 2008
Date : 0th October 2008

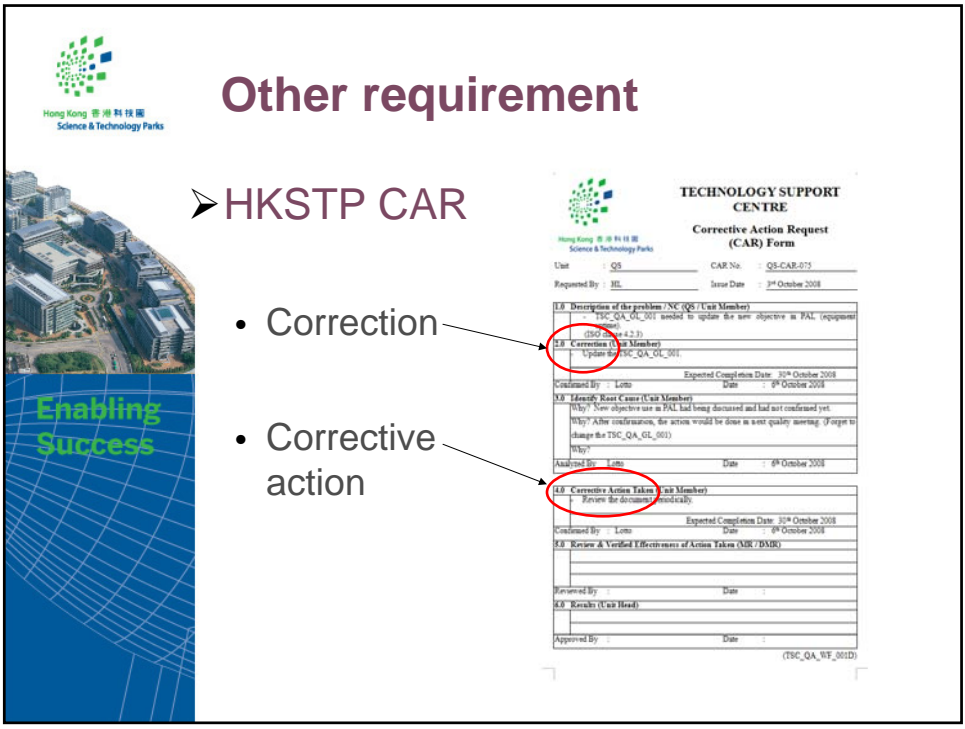
1.3 Review & Verify Effectiveness of Action Taken (SIC / DBMS)

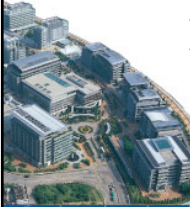
Reviewed By : Date :
Reviewed By (Unit Head) : Date :
Approved By : Date :

(TSC_QA_WF_001D)

Perspective: Value-added through Quality

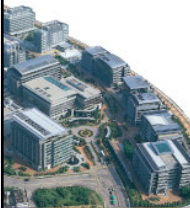
- Key value from ISO 9001:2008
- Customer Satisfaction
 - customer perception
 - outsourced processes
- Customer property
 - intellectual property and personal data





Perspective: Value-added through Quality

- Competence, training and awareness
 - **necessary competence**
- Infrastructure
 - supporting services (such as transport, communication or **information systems**)



Perspective: Value-added through Quality

All value-created is for
CUSTOMER!!



Thank you

Q & A

<http://qualityalchemist.blogspot.com/>

