Collaborating Organizations

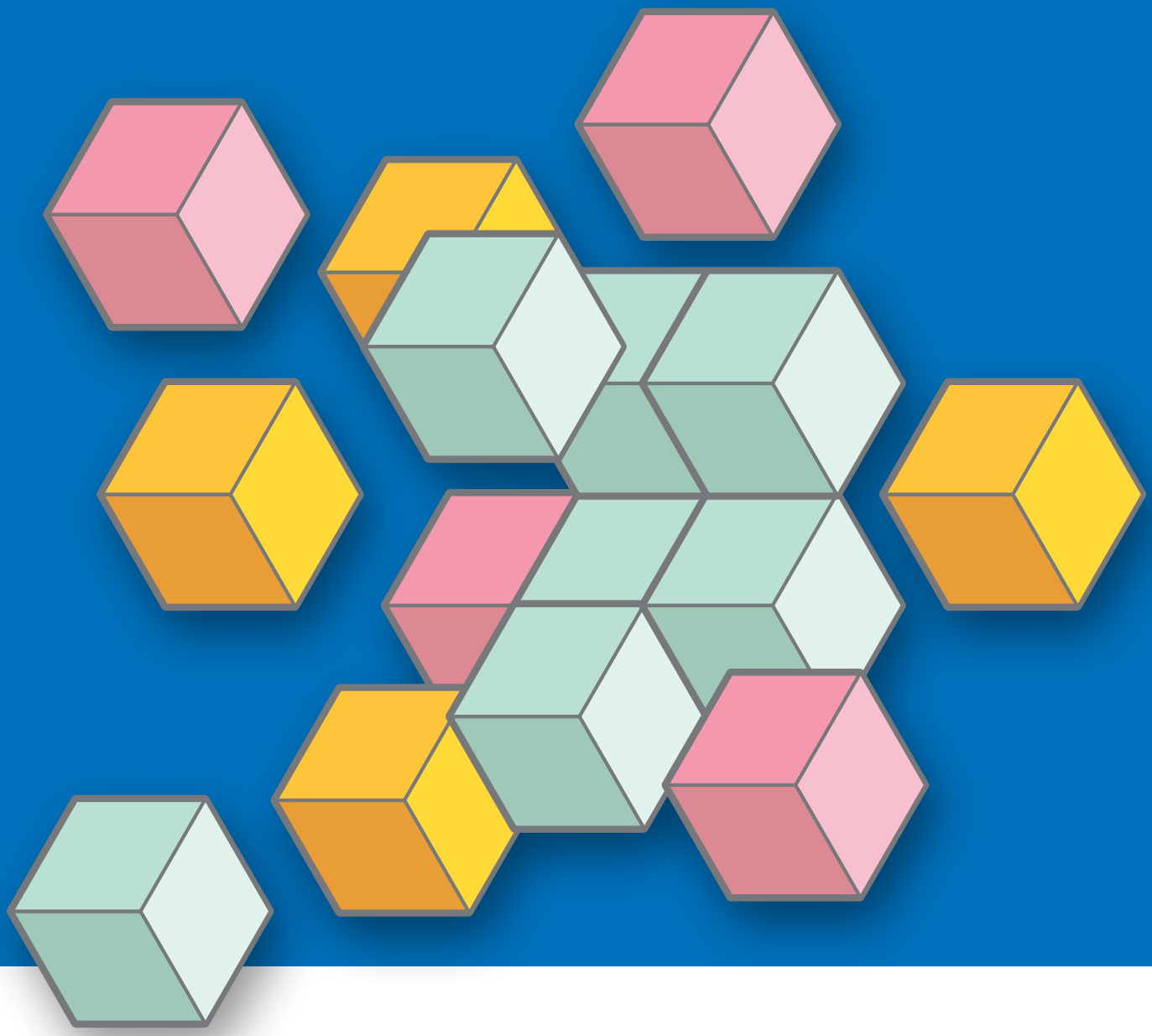
Hong Kong Institution of Certified Auditors
香港專業審核師學會

香港檢測和認證局
The Hong Kong Council for Testing and Certification

資歷架構
Qualifications Framework

ISO 9001:2015 Challenges and Opportunity for Auditors

Testing, Certification and Risk Management



Date • 25 January 2018, Thursday

Venue • Regal Riverside Hotel, Shatin (Hong Kong)

Time • 9:00 a.m. (registration) – 5:00 p.m.

ISO 9001:2015 Challenges and Opportunity for Auditors Testing, Certification and Risk Management

Programme Rundown

Time	Topic	Speaker
09:00 - 09:15	**Registration**	
09:15 - 09:30	**Opening Speech**	**Ir Dr Tommy Lo** President of Hong Kong Institution of Certified Auditors (Hong Kong)
09:30 - 09:35	**Photo taking with speakers**	
09:35 - 10:20	**貫徹新版 ISO 9001 標準 企業面臨的問題、困惑和經驗**	**李平女士** CCAA 高級審核員、GB 9001 起草人 (China)
10:20 - 11:05	**Materials Risk Management System of Housing Authority**	**Ir KS Kwan** Chief Structural Engineer, Hong Kong Housing Authority (Hong Kong)
11:05 - 11:25	**Tea Break**	
11:25- 12:10	**Challenges and Competence of Auditors on Risk ManagementAudit**	**Ir Dr Tommy Lo** President of Hong Kong Institution of Certified Auditors (Hong Kong)
12:10 - 12:30	**Discussion and Q & A**	
12:30 - 14:00	**Lunch**	
14:00 - 14:45	**ISO 31000 Risk Management Requirements for ISO 9001:2015 from the global perspectives**	**Ir C K Cheung** Evaluator, APLAC & PAC (Hong Kong)
14:45 - 15:30	**Latest QMS Certification Status in Singapore**	**Mr Tan Yee Chine** TIC Group, SPRING Singapore (Asian Speaker)
15:30 - 15:50	**Tea Break**	
15:50 - 16:35	**How to Implement and Enhance Risk-based Thinking in PDCA Cycle**	**Mr Thomas Ma** Former Chief Executive Castco Certification Services Ltd. (Hong Kong)
16:35 - 17:00	**Discussion and Q & A**	

ISO9001:2015 Challenges and Opportunity for Auditors
Testing, Certification and Risk Management

李平女士

CCAA 高級審核員、GB 9001 起草人 (China)

貫徹新版 ISO 9001 新版標準面臨的問題、困惑和經驗

香港审核师学会研讨会

贯彻新版ISO9001标准 企业面临的问题、困惑和经验

李 平

- 国培认证培训中心 主任
- CCAA理事、高级审核员、课程评审专家
- CCAA《2015版标准转换培训教材》主要执笔人
- GB9001标准起草人、《QMS国家标准理解与实施》主要执笔人

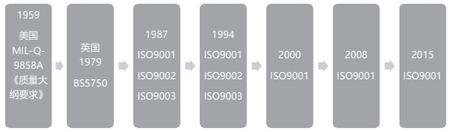
国培/www.necca.org.cn

内 容 介 绍

- 引言
- 外部环境对贯标和认证的影响
- 企业内部面临的问题和困惑
- 经验和体会分享

引 言

ISO 9001标准发展历程



引 言

- ISO9001是3个最有影响力、应用最广泛的标准之一
- 中国--认证大国
  - 管理体系认证证书发证数量第一
  - 中国颁发的认证证书约170多万张，其中QMS证书50多万张，占管理体系认证证书的2/3强
- 中国在ISO的地位日益提升
- 新版标准的新思想、新理念和新要求对企业是挑战

外部环境对贯标和认证的影响

- 政府高度重视质量管理--强调“把推动发展的立足点转到提高质量和效益上来，明确提出开展质量提升行动。9月发布了《国务院关于开展质量提升行动的指导意见》
- 存在诸多问题和不利因素，影响企业贯标和认证的积极性和有效性：
  - 认证乱想不断受到相关方的诟病
  - 认证的公信力和采信度的下降
  - 二方审核的强势增长
- 国标的发布：2016年12月30，留给企业换版的时间不多

企业内部面临的困惑和问题

- 思想转变缓慢。对标准要求的不理解，特别是一些新要求新理念如：
  - 基于风险的思维、4.1、4.1、6.1等
  - 生搬硬套，照抄标准条文，走形式，做样子
- 对体系文件的困惑：数量、结构和形式
- 对成文信息（Documented Information）的困惑
- 重实施轻结果，缺乏绩效评价机制

经验和体会分享

促进观念转变，加深对标准理解

- 培训引导
- 专家讲师至关重要
- CCAA，认监委多次组织国内外知名专家及TC176的专家进行专题演讲
  - 对标准理解的一致性
  - 确保对企业进准确的引导和培训
- 专题研讨或课题研究

经验和体会分享

关于体系文件

- 文件编写
  - 不宜推翻重写
  - 应结合原有文件，补充完善
  - 可以保留质量手册，手册的结构：
    - 采用旧结构、补充新要求(对照表)
    - 采用与新标准一致的结构
    - 采用适用的结构与模式
- 结构&模式
- 文件记录内容与数量
  - 组织自行决定，基于风险

三种模式各有利弊

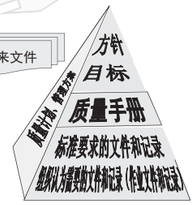
经验和体会分享

关于体系文件的架构

保留传统架构

打破传统架构，融入业务过程形成适合的文件架构和形式

外来文件



- 企业管理标准
- 管理手册
- 过程规范
- 规章制度
- 实施细则
- 流程图

经验和体会分享

4.1和4.2条款的实施

4. 1/4. 2

最高管理者

建立机制

- 方式方法
- 职责权限
- 时机和频次
- 记录

理解认同支持

执行

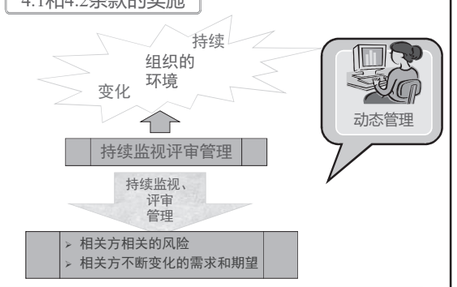
实施证据

可形成表格

动态管理

经验和体会分享

4.1和4.2条款的实施



经验和体会分享

关于基于风险的思维

最高管理者应高度重视

Risc-based thinking

- 不是要求 是理念 是思想方法
- 贯穿QMS每一个过程
- 策划QMS及换版时，充分考虑体系面临的风险和机遇

2

3

ISO9001:2015 Challenges and Opportunity for Auditors
Testing, Certification and Risk Management

Ir KS Kwan
Chief Structural Engineer, Hong Kong Housing Authority (Hong Kong)

Materials Risk Management System of Housing Authority

经验和体会分享

6.1风险和机遇的应对

各个过程均存在不同程度的风险和机遇，应全员参与识别和控制

最高管理层高度重视并亲自参与风险和机遇的识别，特别是组织层面的。

Action to address risks and opportunities

动态管理，监视和评审变化，及时应对

考虑原有规范、文件或规定中包含的应对措施，可直接引用或补充完善。

必要的记录，以便于及时追溯，也为该项工作的有效实施提供证据。

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经验和体会分享

7.5 成文信息

- 概念的理解：文件和记录
  - 仍可沿用以前习惯的术语，如“文件”“记录”“质量手册”“程序文件”或惯用的公文形式及名称，重要的是适用和有效。
- 仍然可以保留原来的文件控制程序或记录控制程序，也可以将其整合
- 应考虑电子形式的成文信息的控制，如：
  - 不同级别的只读访问和规定权限访问的电子系统
  - 密码保护或身份识别（ID）准入等方式
  - 信息安全问题和数据备份也应纳入考虑范畴。

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经验和体会分享

7.5 成文信息

- “保持成文信息”可以是：
  - 书面文件，如程序、手册、表格和检查表中包含的信息
  - 计算机硬盘或CD光盘中存放的文件
  - 录音、录像、样板/示范、照片或图样
  - 存储于云端和下载到智能手机或其他电子设备上的信息，
- “保留成文信息”，是指用于证明是否已经满足了要求的信息，如记录、报告、档案等证实性文件。

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经验和体会分享

建立绩效评价机制

- ISO001标准更注重结果，强调绩效评价，实现预期结果
  - 不应停留在仅仅进行监视、测量和分析的阶段
  - 要考虑如何对分析的数据进行评价。
- 应建立绩效评价机制
  - 确定监视、测量、分析和评价的方式方法，时机频次
  - 各个过程制定可测量的评价指标
  - 对分析的数据进行评价，作出结论，为改进提供输入

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Hong Kong Institution of Certified Auditors
2018 Workshop

ISO9001:2015 Challenges and Opportunity for Auditors
Testing, Certification and Risk Management

Material Risk Management System of Housing Authority

Ir. KS Kwan
Chief Structural Engineer/DC
Housing Authority
25 Jan. 2018

1

Background of Risk Assessment of Building Materials

In response to the Report of the Commission of Inquiry (CoI) into Excess Lead found in Drinking Water

Recommendation para. 487 (12)

"HA should in consultation with WSD, review all the materials to be used in the construction of PRH estates....."

Recommendation para. 487 (13)

"HA should put in place a robust system to monitor the compliance of the plumbing installations ....."

2

Action Plan

1 **Monitoring of All Materials**

- Conduct a comprehensive **risk assessment** on **all** building materials
- Review material control system including
  - **purchasing**
  - **delivery**
  - **storage**
  - **use of materials effected by main contractors**

2 **Managing the Risk on Contractors using materials deviated from the Specification**

- Embracing a wider scope which includes but not limited to plumbing installations
- Making reference to ISO 31000 : Risk Management – Principles and Guidelines

3

ISO 31000 Risk Management Model

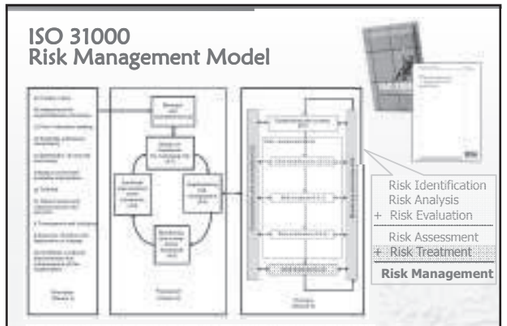

Figure 1 — Relationships between the risk management principles, framework and process

Source: BS ISO 31000:2009

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Risk Management

Purpose

Manage the risk on contractors using materials deviated from the Specification

Risk Identification

Scope of Assessment

HKHA Specification Library 2014 Edition Specification clauses (.M) on building & engineering materials used in -

Architectural	1100+	Civil Engineering	200+
Building Services	600+	Geotechnical Engineering	60+
Structural	250+	Soft Landscaping	100+
		TOTAL	**2300+**

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Categories of Materials

Materials
Rarely Used Materials
Non-Materials

Round up figures

Categories	Architectural	Building Services	Structural	Civil Engineering	Geotechnical Engineering	Soft Landscape	Total
Materials	650	500	85	100	30	50	1415
Rarely Used Materials	250	5	5	40	5	20	325
Non-Materials	200	95	160	60	25	40	580
	1100	600	250	200	60	110	**2320**

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Risk Analysis

To work out the Risk Level

Risk Level = Likelihood x Consequence (L x C)

Likelihood L (chances of occurrence)		1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
Frequent	5	5	10	15	20	25
Likely	4	4	8	12	16	20
Possible	3	3	6	9	12	15
Unlikely	2	2	4	6	8	10
Rare	1	1	2	3	4	5

Risk Level = L x C

Consequence C
(magnitude of impact)

Risk Analysis

Likelihood Aspects

Likely occurrence of the following aspects leading to non-compliance

1	Financial Benefit	p,u
2	Effort Saving	p,u
3	Escape from Checking	p,d,s,u
4	Lack of Awareness/Knowledge	p,d,s,u
5	Lack of Skill/Workmanship	s,u
6	Deficiency Record	p,d,s,u
7	New Material	p,d,s,u

Assess Likelihood at different phases

Purchasing p
Delivery d
Storage Control s
Use of Material u

Such that control measures can be effectively applied at the particular time location in the building construction period

Risk Analysis

To work out CONSEQUENCE

Item No.	Statutory non-compliance (Ordinance /Regulation...)	Functionality	Safety (Within scope of Spec)	Health (Within scope of Spec)	Project Progress	Total Count	Insignificant 5-8 (4)	Minor 9-12 (4)	Moderate 13-16 (4)	Major 17-20 (4)	Catastrophic 21-25 (5)	Overall Consequence (C)
135	5	5	5	5	5	25	1	2	3	4	5	5

Step 1 Give *rating* to each Consequence aspect

Step 2 *Add* up all the ratings of the 5 Consequence aspects

Step 3 Locate the *banding* of the Overall Consequence

Overall Consequence level is the banding

	Banding	Score range	Rating
1	Insignificant	5-8	1
2	Minor	9-12	2
3	Moderate	13-16	3
4	Major	17-20	4
5	Catastrophic	21-25	5

Overall Consequence = 5

Risk Analysis

To work out Risk Score/Level

Risk Score = Likelihood x Consequence (L x C)
= 4 x 5 = 20

Risk Level = A

Item No.	Title of Specification Section	Clause No.	Likelihood of Occurrence of Non-compliance: Financial Benefit (Purchase Use)	Effort Saving (Purchase Use)	Escape from Checking (Purchase Delivery Storage Use)	Lack of Awareness/ Knowledge (Purchase Delivery Storage Use)	Lack of Skill / Workmanship (Storage Use)	Deficiency Record (Purchase Delivery Storage Use)	New Material (Purchase Delivery Storage Use)	Total Count	Rare 7-11 (5)	Unlikely 12-17 (6)	Possible 18-23 (6)	Likely 24-29 (6)	Frequent 30-35 (6)	Overall Likelihood (L)
135	TIMBER DOORSETS	COMS. M040.7	5	5	3	3	3	5	1	25	1	2	3	4	5	4

Item No.	Statutory non-compliance (Ordinance /Regulation...)	Functionality	Safety (Within scope of Spec)	Health (Within scope of Spec)	Project Progress	Total Count	Consequence / Impact on Risk Criteria: Insignificant 5-8 (4)	Minor 9-12 (4)	Moderate 13-16 (4)	Major 17-20 (4)	Catastrophic 21-25 (5)	Overall Consequence (C)	Total Risk Score (LxC) max 25	Risk Level
135	5	5	5	5	5	25	1	2	3	4	5	5	20	A

Risk Assessment on All Building Materials

Risk Analysis

Consequence of the following Risk Criteria

Assess the consequence (magnitude of impact) of risks

1. Statutory Non-compliance
2. Functionality
3. Safety to workers, users, 3rd party, properties
4. Health to workers, users, public
5. Project Progress

Risk Analysis

To Categorize the Risk into Levels

A = Extreme B = Moderate C = Low

B split into priority B1 & B2 for stage review

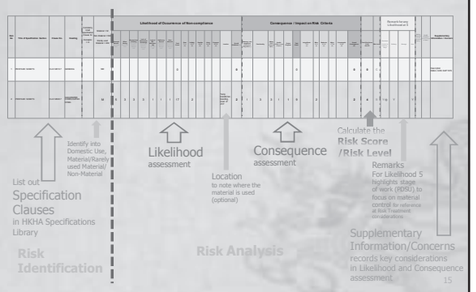
Likelihood L (chances of occurrence)		1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
Frequent	5	5	10	15	20	25
Likely	4	4	8	12	16	20
Possible	3	3	6	9	12	15
Unlikely	2	2	4	6	8	10
Rare	1	1	2	3	4	5

B2 B1 C A

Consequence C
(magnitude of impact)

Risk Assessment Worksheet Layout

Risk Identification + Risk Analysis



List out Specification Clauses in HKHA Specifications Library

Identify into Domestic Use, Material/Rarely used Material/ Non-Material

Likelihood assessment

Location to note where the material is used (optional)

Consequence assessment

Calculate the Risk Score /Risk Level

Remarks For Likelihood 5 highlights stage of work (BP01) to focus on material control for reference at Risk Treatment considerations

Supplementary Information/Concerns records key considerations in Likelihood and Consequence assessment

Risk Identification

Risk Analysis

Risk Assessment on All Building Materials

Risk Assessment Results

Round up figures

Risk Level	Architectural	Building Services	Structural	Civil Engineering	Geotechnical Engineering	Soft Landscape	Total
A	300	100	50	40	10	5	505
B	500	40	30	50	10	10	640
C	300	460	170	110	40	95	1175
	1100	600	250	200	60	110	2320

General Principles applicable to all disciplines in risk assessment/treatment

1. The risk assessment is based on the **normal life cycle** of the individual material
2. The risk assessment is based on **known information** of "building materials **impact on human health**" shown in the existing Specifications*
3. The extent of consideration of risk is limited to the **immediate associated risk** caused by the material deviation from the Specifications

* SAFETY & HEALTH concerns not explicitly indicated at the Specification (i.e. **out of scope** of the specification) but suspected likely to have impact on safety and/or health are assessed as "**Suspected Safety / Health Concerns**" and addressed at risk treatment stage

Risk Analysis

To work out LIKELIHOOD

Item No.	Title of Specification Section	Clause No.	Likelihood of Occurrence of Non-compliance: Financial Benefit (Purchase Use)	Effort Saving (Purchase Use)	Escape from Checking (Purchase Delivery Storage Use)	Lack of Awareness/ Knowledge (Purchase Delivery Storage Use)	Lack of Skill / Workmanship (Storage Use)	Deficiency Record (Purchase Delivery Storage Use)	New Material (Purchase Delivery Storage Use)	Total Count	Rare 7-11 (5)	Unlikely 12-17 (6)	Possible 18-23 (6)	Likely 24-29 (6)	Frequent 30-35 (6)	Overall Likelihood (L)
135	TIMBER DOORSETS	COMS. M040.7	5	5	3	3	3	5	1	25	1	2	3	4	5	4

Step 1 Give *rating* to each Likelihood aspect

Step 2 *Add* up all the ratings of the 7 Likelihood aspects

Step 3 Locate the *banding* of the Overall Likelihood

Overall Likelihood level is the banding number

	Banding	Score range	Rating
1	Rare	7-11	1
2	Unlikely	12-17	2
3	Possible	18-23	3
4	Likely	24-29	4
5	Frequent	30-35	5

Overall Likelihood = 4

Stakeholders' Engagement

1. **Commissioned HKQAA** (Hong Kong Quality Assurance Agency) for a gap assessment with ISO 31000 standards while conducting the risk assessment
2. **Partnering with building contractors**
   Contractors' input on "effort saving", "lack of awareness/knowledge" and "lack of skill/workmanship", are representative views of the industry
3. **Engage other stakeholders**
   including HA members, government departments, trade associations, institutions, academia, professional service providers and suppliers etc. to obtain their views

Risk Evaluation & Risk Treatment

For each material, the following areas are evaluated on current controls C and proposed enhancements E

	Submission			Delivery				Storage		Use		
ISO 9001	Product Certificate	DASM-F8210	SIT	SIT / contractor	MMO	C&M		SIT / contractor		SIT / contractor		Spec Team
C E	C E	C E	C E	C	E	C E		C E		C E		C E

SIT Site Inspection Team
MMO Material Monitoring Officer
C Current Control
E Proposed Enhancement

Risk Evaluation & Risk Treatment

For each material, the following areas are evaluated on
current controls **C** (Risk Evaluation) & proposed enhancements **E** (Risk Treatment)
Based on **risk analysis results**
Focus on **purchase, delivery, storage, use**

Areas	Evaluate Current Controls	Proposed Enhancement
ISO 9001	Evaluate adequacy of ISO 9001 requirement for the material manufacturers, suppliers	Include more materials for ISO 9001 accreditation
Product Certificate	Evaluate adequacy of Product Certificate requirements for the materials	Include more materials for Product Certificate requirement
DASM-F6210	Evaluate adequacy of site inspection	Tighten up site controls
Purchase	Purchase is Contractor's own strategy, material control at Delivery stage	
Submission	Evaluate adequacy of submission requirements	Add submission requirements to demonstrate compliance with Specifications
Delivery	Evaluate adequacy of controls during on- site delivery by SIT, C&M	SIT tighten up inspection checks (DASM-F6210) and field/laboratory tests MMO checks all delivery notes C&M tighten up surveillance checks/tests
Storage	Evaluate adequacy of storage condition checking	Include more materials for storage condition checking
Use	Evaluate adequacy of site inspection	Tighten up site inspection
Specifications	Revise HKHA Specification Library, Technical Guides, Site Inspection procedures	

Risk Evaluation & Risk Treatment

General Approach

Based on results of the **risk analysis**, focus on **purchase, delivery, storage** and **use**, evaluate the existing control measures, and determine following treatment actions as necessary -

- Keep **Existing control** measures if found adequate
- Enhance existing control measures
- Develop new control measures
- Increase frequency of **material surveillance** check
- Extend the material surveillance check to cover more materials
- Review and enhance **specifications, technical guides, site inspection procedures**

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Outcome of Risk Treatment

Risk assessment final results will form the basis for establishing the material control mechanism -

Incorporate into the **enhanced quality control system on material compliance checking and monitoring** which will include updating of

- Contract requirements
- Specifications
- Technical guides
- Site inspection procedures

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RISK MANAGEMENT OF BUILDING MATERIALS IS A CONTINUOUS PROCESS

* * *

Review on an annual basis

Continuously enhance material quality control system with stakeholders and experts

Regularly review and maintain the effectiveness of the system

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Thank you

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Ir Dr Tommy Lo
President of Hong Kong Institution of Certified Auditors (Hong Kong)

Challenges and Competence of Auditors on Risk Management Audit

Hong Kong Institution of Certified Auditors 香港專業審核師學會

Collaborating Organizations

Challenges and Competence of Auditors On Risk Management Audits

Dr. Tommy Y Lo
President, Hong Kong Institution of Certified Auditors
盧耀博士工程師
香港專業審核師學會主席

25 January 2018, Regal Riverside Hotel (Hong Kong) 1

2009 Chief Executive's Policy Address

Testing and Certification Services was one of the six pillar industries for propelling Hong Kong towards a knowledge based economy

Setting up

Hong Kong Council for Testing and Certification (HKCTC)

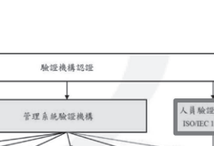
Four trades are included in the Development Plan for the testing & certification Industry

- Chinese Medicine
- Construction Materials
- Food
- Jewelry

Brand

"Tested in Hong Kong, Certified in Hong Kong"

to promote the reputation of Hong Kong **to a very good standard throughout the world**;



What is an audit ?

- An audit is conducted in accordance with the specified requirements in order to find out areas of non-conformities for corrections and/or observations for improvements. [ISO9001, 14001, 22000, product certification scheme]

3rd Party Quality Audit

- Third party audit by a government accredited certification body.
- Generic requirements on QMS applicable for any organizations.
- In Hong Kong, all contractors and consultants to be certified to ISO 9001.

Technical Audit

- Verify that the building components constructed in accordance with the approved drawings and specifications
- Approved drawing specify the configuration of the structure, specification define the materials grade and materials standard
- Construction materials audit is a principal and critical part of the technical audit.

Product Certification Schemes

Product Schemes Auditors (HK)

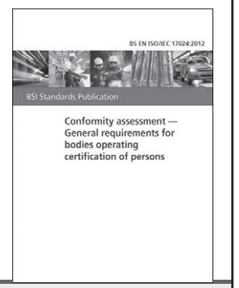
Auditor: A nominee of the Certification Body appointed to carry out assessments.

Most of the schemes required Registered IPC or Hong Kong Institution of Certified Auditors (HKICA) Lead Auditor in QMS or equivalent.

Hong Kong Institution of Certified Auditors 香港專業審核師學會

Certification of Persons

質量管理體系人員認證計劃以符合
ISO / IEC 17024國際認證的要求



Hong Kong Institution of Certified Auditors 香港專業審核師學會

Certification of Persons

Background of HKICA Established in 2006

- A non-profit making organization for Quality Management Auditors
- Executive Board comprises members from universities, public authorities, governmental organizations, certification bodies, management systems consultants in Hong Kong
- meet the ever changing need of these industries and the expectation of the community; and a bridging function of certification services for all industrial trades of local, Asian and international enterprises.
- HKICA provides fair and impartial certification service to ISO17024 international standard for Management System auditors and internal auditors (quality, environmental, occupational health & safety, food safety, laboratory and other) in affirmation of their competency in professional skills and knowledge.

Hong Kong Institution of Certified Auditors 香港專業審核師學會

Certification of Persons

Established in 2006

HKICA Vision

- To become a renowned public personnel certification body in the Asia Pacific Region
- To promote the status of ISO auditors to the public as a profession;

Hong Kong Institution of Certified Auditors 香港專業審核師學會

HKICA becomes a Certification Body for Certification of Persons Since 2016
ISO17024 : 3rd Party Impartial Certification for Professionalism Auditor

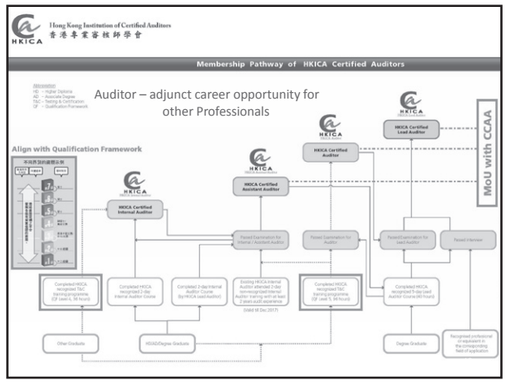
中國合格評定國家認可委員會（CNAS）肖建華秘書長頒發

質量管理體系人員認證機構認可證書
予
香港專業審核師學會（HKICA）會長盧耀博士

The award ceremony from China National Accreditation Service to The Hong Kong Institution of Certified Auditors
June 2016

中國認證認可協會 / 香港專業審核師學會
達成質量管理體系審核師認證的互認協議

The MoU signing ceremony between Hong Kong Institution of Certified Auditor 會長盧耀博士 / China Certification and Accreditation Association 生幾秘書長
August 2016



Hong Kong Institution of Certified Auditors 香港專業審核師學會

Auditor is a Professional
Quality Management Auditors is recognized as one of the 58 Enlisted Professionals in Mainland

国家职业资格目录清单

专业技术人员职业资格（共计58项）

序号	职业资格名称	实施部门（单位）	设定依据
1	教师资格	教育部	《中华人民共和国教师法》 《教师资格条例》（国务院令第188号） 《〈教师资格条例〉实施办法》（教育部令2005年第10号）
3	法律职业资格	司法部	《中华人民共和国律师法》 《中华人民共和国法官法》 《中华人民共和国检察官法》 《中华人民共和国公证法》
9	注册建筑师	全国注册建筑师管理委员会及省级注册建筑师管理委员会	《中华人民共和国建筑法》 《中华人民共和国注册建筑师条例》（国务院令第184号） 《建设部、人事部关于建立注册建筑师制度及有关工作的通知》（建设〔1994〕第098号） 《建设工程勘察设计管理条例》（国务院令第293号）
10	监理工程师	住房城乡建设部、交通运输部、水利部、人力资源社会保障部	《中华人民共和国建筑法》 《建设工程质量管理条例》（国务院令第279号） 《注册监理工程师管理规定》（建设部令2006年第147号）
14	建造师	住房城乡建设部、人力资源社会保障部	《中华人民共和国建筑法》 《注册建造师管理规定》（建设部令2006年第153号） 《建造师执业资格制度暂行规定》（人发〔2002〕111号）
15	勘察设计注册工程师 注册结构工程师	住房城乡建设部、人力资源社会保障部	《中华人民共和国建筑法》《建设工程勘察设计管理条例》（国务院令第293号） 《勘察设计注册工程师管理规定》（建设部令2006年第137号）
	注册土木工程师	住房城乡建设部、交通运输部、水利部、人力资源社会保障部	《注册土木工程师（岩土）执业资格制度暂行规定》（人发〔2002〕35号） 《注册土木工程师（水利水电工程）制度暂行规定》（国人部发〔2006〕38号） 《注册土木工程师（港口与航道工程）执业资格制度暂行规定》（人发〔2006〕22号） 《勘察设计注册土木工程师（道路工程）制度暂行规定》（国人部发〔2007〕44号）
51	认证人员职业资格	质检总局	《中华人民共和国认证认可条例》（国务院令第390号）
61	出版专业技术人员职业资格	新闻出版广电总局、人力资源社会保障部	《出版管理条例》（国务院令第343号） 《音像制品管理条例》（国务院令第341号） 《出版专业人员职业试行条例》（职改字〔1988〕第41号） 《出版专业技术人员职业资格考试暂行规定》（人发〔2001〕56号）
53	统计专业技术资格	国家统计局、人力资源社会保障部	《统计专业职务试行条例》（职改字〔1986〕第2号） 《统计专业技术资格考试暂行规定》（人职发〔1993〕1号） 《关于印发高级统计师资格评价办法（试行）的通知》（人社部发〔2011〕90号）

Hong Kong Institution of Certified Auditors 香港專業審核師學會

Certification of Persons

Membership

Fellow Member FHKICA 資深會員 179

Member MHKICA 會員 191

Personnel Schemes

ISO 9001
ISO 14001
ISO/IEC17025
OHSAS 18001
ISO 22000
ISO 17024

Personnel Registration

Registered Lead Auditor	67	Certified Lead Auditor	45
Registered Auditor	32	Certified Auditor	4
Registered Internal Auditor	27	Certified Assistant Auditor	6
QMS Quality Manager	39	Certified Internal Auditor	8
Laboratory Manager	7		
EMS Quality Manager	12		
Welding Inspector	16		
Product Certification Tech Auditor	18		

Personnel Registration HKICA

Hong Kong Institution of Certified Auditors 香港專業審核師學會

ISO9001: Challenges and Opportunity

Organization had risk management framework

Risk owners would be in different position and activities:
- Risk in construction projects included "Political", "Financial", "Design", "Construction", "Environmental", "Legal/Contractual", "Physical", "Economical", "Technical" and "Operational".

Audit plan for companies' risk has to consider impacts on:
- "Brand/Reputation", "Customers", "Profit", "Product Safety", "People Safety", "Business Continuity", "Product/Service Process", "Cost of Poor Quality" and "Business Strategy".

Audit INVOLVE professional knowledge, such as Engineer (Technical/operational risk based audit)

"Risk Based Auditing – Engineering and Construction" by Richard Green

Competency
- Auditor with professional knowledge/
- Professionals with audit knowledge

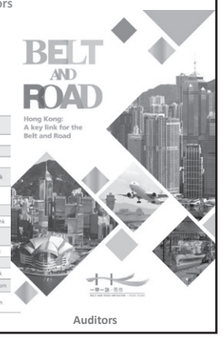
Hong Kong Institution of Certified Auditors 香港專業審核師學會

About Hong Kong Institution of Certified Auditors

Certified by CNAS in May 2016
MoU arrangement with CCAA in Sept 2016
Belt and Road
• • • • • • • • • • • • • • → **Testing and Certification**

IV. Professional Organisations

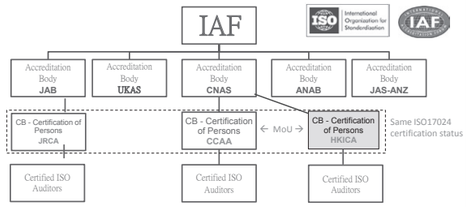
Organisation	Office Tel	Email
Hong Kong Coalition of Professional Services (http://www.cps.hk)	852-2169 3128	info@cps.hk
Hong Kong Institute of Chartered Secretaries (https://www.hkics.org.hk)	852-2881 6177	ask@hkics.org.hk
Hong Kong Association of Banks (https://www.hkab.org.hk)	852-2521 1169	info@hkab.org.hk
Hong Kong Federation of Insurers (http://www.hkfi.org.hk)	852-2520 1868	hkfi@hkfi.org.hk
Hong Kong Securities Association (http://www.hksa.com.hk)	852-2541 8832	info@hksa.com.hk
Hong Kong Institute of Certified Public Accountants (http://www.hkicpa.org.hk)	852-2287 7228	hkicpa@hkicpa.org.hk
Hong Kong Institution of Certified Auditors (http://www.hkica.org/hk)	852-2789 2389	info@hkica.org
Hong Kong Bar Association (http://www.hkba.org)	852-2869 0210	info@hkba.org
Law Society of Hong Kong (http://www.hklawsoc.org.hk)	852-2846 0518	dcom@hklawsoc.org.hk
Hong Kong International Arbitration Centre (http://www.hkiac.org)	852-2525 2381	sg@hkiac.org
Hong Kong Society of Architects (http://www.hksa.net)	852-2511 6323	hksaoc@hkia.org.hk
Hong Kong Institute of Surveyors (http://www.hkis.org.hk)	852-2526 3679	info@hkis.org.hk
Hong Kong Institution of Engineers (https://www.hkie.org.hk)	852-2895 4446	hkie-sec@hkie.org.hk
Hong Kong Institute of Planners (http://www.hkip.org.hk)	852-2915 6212	hkiplanner@netvigator.com
Hong Kong Institute of Landscape Architects (http://www.hkila.com)	852-2896 2833	secretariat@hkila.com



Auditors

Hong Kong Institution of Certified Auditors 香港專業審核師學會

HKICA becomes a Certification Body for Certification of Persons Since 2016
ISO17024 : 3rd Party Impartial Certification for Professionalism Auditor



HKICA accredited by 中国合格评定国家认可委员会 (CNAS) will have the same personnel accreditation status with中國認證認可協會(CCAA) so that Hong Kong auditors may work legally in China Mainland.

Hong Kong Institution of Certified Auditors 香港專業審核師學會

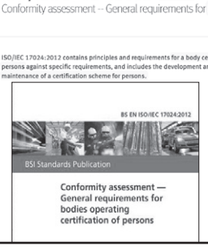
International Organization for Standardization
Great things happen when the world agrees

Store > Standards catalogue > Browse by ICS > 03 > 03.120 > 03.120.20 > ISO/IEC 17024:2012

ISO/IEC 17024:2012 Preview

Conformity assessment -- General requirements for bodies operating certification of persons

ISO/IEC 17024:2012 contains principles and requirements for a body certifying persons against specific requirements, and includes the development and maintenance of a certification scheme for persons.



Hong Kong Institution of Certified Auditors 香港專業審核師學會

Way forwards

Great things happen when the world agree

Professionalism of certification professionals
- competence, impartiality, reliability

A transformation of management strategy

Internal Audit Department

Hong Kong Institution of Certified Auditors
香港專業審核師學會

With the revised standards, there are new requirements for **greater leadership involvement** in the management system, which must be evident **not only in the organization's processes, but in its policies, objectives, and overarching strategic direction.**

An effective Quality Management System cannot be achieved without the commitment of the organization's leadership, the revised ISO standard has codified this requirement into seven broad areas.

- Responsibility
- Policy
- Objectives
- Integration
- Compliance
- Operational Awareness, and
- Authorities

WHO leader ? Who know …difference process? Who is more important (responsible) to audit (internal or external?) Audit

Maturity models, not just compliance alone

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香港專業審核師學會

Organization had risk management framework

Risk owners would be in different position and activities:
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Audit plan for companies' risk has to consider impacts on:
- "Brand/Reputation", "Customers", "Profit", "Product Safety", "People Safety", "Business Continuity", "Product/Service Process", "Cost of Poor Quality" and "Business Strategy".

Audit INVOLVE professional knowledge, such as Engineer (Technical/operational risk based audit)

Board knowledge input required
- Auditor with strong audit experience
- Professionals with audit knowledge

"Risk Based Auditing – Engineering and Construction"
by Richard Green (Head of IRCA Technical Services)

Hong Kong Institution of Certified Auditors
香港專業審核師學會

Risk of Internal Audit

All ISO based standards require that internal audits be performed periodically to ensure that the management system complies with requirements of the respective standard. (Internal Auditor contribute to risk and opportunity??)

Risk of System

When internal audits follow the identical process over and over, the internal auditors tend to become bored, those being audited tend to view the ordeal as a waste of time, and **management interest tends to fade away** (non-productive).

In many organizations internal audits deteriorate to an obligation necessary to meet the requirements of the standard rather than **a value adding process**. To keep internal audits fresh, the audit process must be examined.

Who take care?? We need a designated person

William Houser, Eagle Force, Inc
Keeping Internal Audits Fresh
2016 ISO 9000 World Conference, Orlando, USA. 21-22 March 2016

Hong Kong Institution of Certified Auditors
香港專業審核師學會

How Caterpillar improves quality performance and adherence to its Quality Management System through an internal—but independent—2nd party audit group ?

A "siloed" approach through a centrally coordinated team comprised of—or in close collaboration **with—internal subject matter experts in various QMS processes.**

The team facilitates deployment of a single, comprehensive Quality Management System consisting of best practices observed throughout the enterprise.

The team assesses the effective implementation of the Quality Management System, and through its experience, brings value to the **audit program by propagating these best practices as they (include other professionals) are developed**.

William Kovacich, Caterpillar, Inc.
Value Added Auditing
2016 ISO 9000 World Conference, Orlando, USA. 21-22 March 2016

Hong Kong Institution of Certified Auditors
香港專業審核師學會

Collaborating Organizations

Challenges and Competence of Auditors On Risk Management Audits

Dr. Tommy Y Lo
President, Hong Kong Institution of Certified Auditors
盧耀博士工程師
香港專業審核師學會主席

THANK YOU

25 January 2018, Regal Riverside Hotel (Hong Kong) 23

Ir C K Cheung
Evaluator, APLAC & PAC (Hong Kong)

ISO 31000 Risk Management Requirements for ISO 9001:2015 from the global perspectives

ISO 9001:2015
Quality Management System Requirements – Risk Management

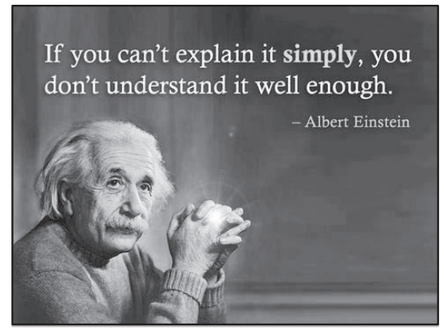
CK Cheung
APLAC & PAC Evaluator
Founding President of HKICA

IAF & PAC Structure of MLA

		Structure of the PAC MLA							
	Level 1	ISO/IEC 17011							
Main Scope	Level 2	Management Systems Certification					Product	GHG Validation Verification	Persons
	Level 3	ISO/IEC 17021-1					ISO/IEC 17065	ISO 14065	ISO/IEC 17024
Subscopes	Level 4	ISO/IEC 17021-3	ISO/IEC 17021-2	ISO TS 22003	ISO/IEC 27006	ISO 50003	GLOBAL G.A.P. IFA General Regulations	N/A	N/A
	Level 5	ISO 9001 QMS	ISO 14001 EMS	ISO 22000 FSMS	ISO/IEC 27001 ISMS	ISO 50001 EnMS	GLOBAL G.A.P. IFA CPCCs	N/A	N/A

ISO9001 有用嗎?
還是它只是一個遊戲

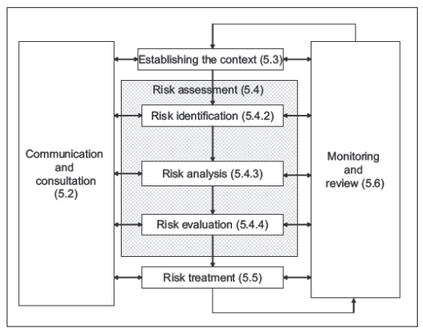
- 視乎企業的態度
- 系統中所訂定的目標的水準
- 品質管制系統的可執行性
- 最高層管理的承諾
- 是一件整體工作人員的工作, 而不是一個個人的工作 (品質經理)
- 培訓



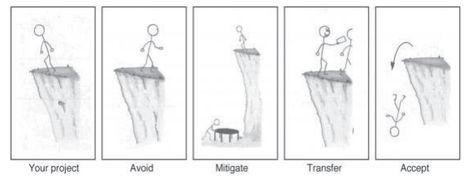
ISO 9001:2008

Quality Policy
Quality Objective
Corrective Action
Preventive Action
Internal Audit
Management Review

Preventive Action

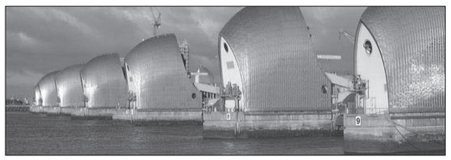


Risk Management



Preventive Action

River Thames Flood Barrier in London



To Prevent Flooding of London in 1 to 200 year Storm

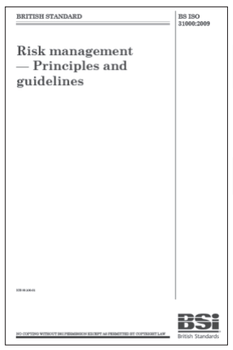
ISO9001:2015

"Risk" & "Opportunity"

Risk Management

品質是甚麼?
達到或超越客戶所陳述和
意味的要求

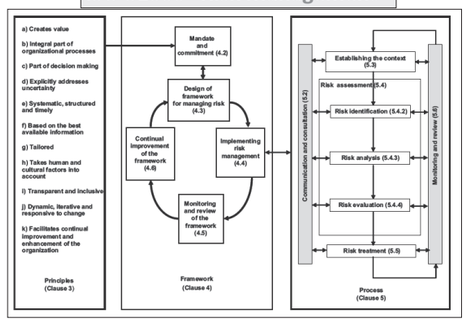
What is quality ?
Meet customer requirement
Exceed their expectation

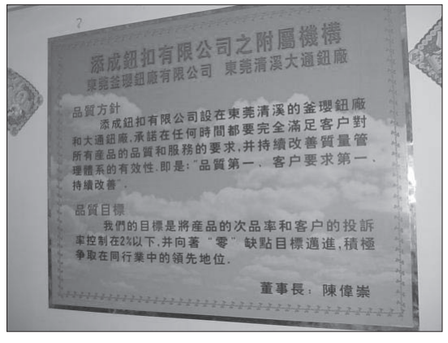


ISO31000:2009

Risk Management

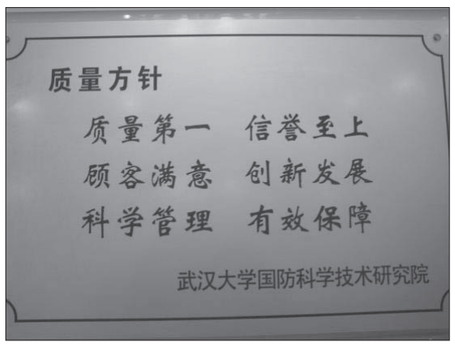
ISO 31000 "Risk Management"

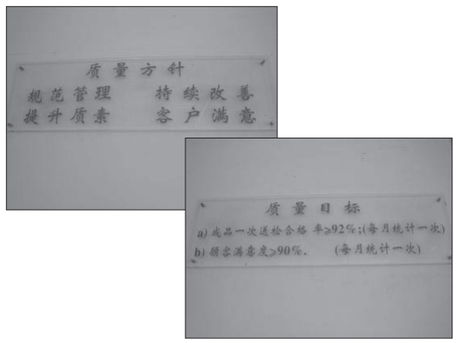




ISO9001:2015
What is "Risk" ?

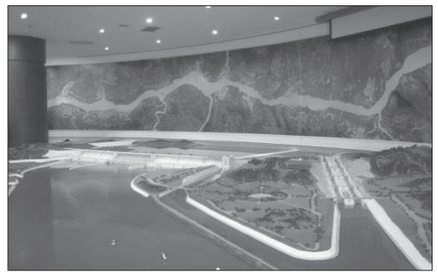
Risk





Fire in a Ship in the Ocean

中國三峽工程 Three Gorges Dam



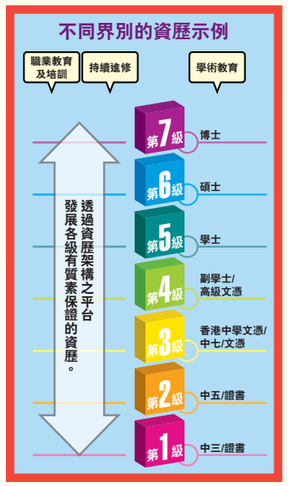
ISO9001:2015 Challenges and Opportunity for Auditors
Testing, Certification and Risk Management

Hong Kong Institution of Certified Auditors
香港專業審核師學會

Membership Pathway of HKICA Certified Auditors

Abbreviation
HD - Higher Diploma
AD - Associate Degree
T&C - Testing & Certification
QF - Qualification Framework

Align with Qualification Framework



HKICA Internal Auditor
HKICA Certified Internal Auditor

HKICA Assistant Auditor
HKICA Certified Assistant Auditor

HKICA Auditor
HKICA Certified Auditor

HKICA Lead Auditor
HKICA Certified Lead Auditor

MoU with CCAA

Completed HKICA recognized T&C training programme (QF Level 4, 36 hours)

Completed HKICA recognized 2-day Internal Auditor Course

Completed 2-day Internal Auditor Course (by HKICA Lead Auditor)

Existing HKICA Internal Auditor attended 2-day non-recognized Internal Auditor training with at least 2 years audit experience
(Valid till Dec 2017)

Completed HKICA recognized T&C training programme (QF Level 5, 96 hours)

Completed HKICA recognized 5-day Lead Auditor Course (40 hours)

Other Graduate

HD/AD/Degree Graduate

Degree Graduate

Recognised professional or equivalent in the corresponding field of application

Passed Examination for Internal / Assistant Auditor

Passed Examination for Auditor

Passed Examination for Lead Auditor

Passed Interview

Experience Requirements

HKICA Certified Lead Auditor
- 15 years working experience (12 years quality-related) OR HKICA certified auditor with 6 years post membership quality-related experience; AND
- At least 3 audits obtained within 3 years before application and minimum 12 audit days (8 days on site)

Other Professional Route
- In the corresponding field engaged in professional work for more than 15 years OR
- Prominent achievements in management theory and practice in the corresponding field

HKICA Certified Auditor
- 4 years working experience (2 years quality-related) OR HKICA certified assistant auditor with 3 years post membership audit experience; AND
- At least 4 audits obtained within 3 years before application and a minimum 20 audit days (12 days on site)

HKICA Certified Assistant Auditor
- HKICA certified internal auditor with 1 year post membership audit experience OR
- Existing HKICA internal auditor with 3 years audit experience

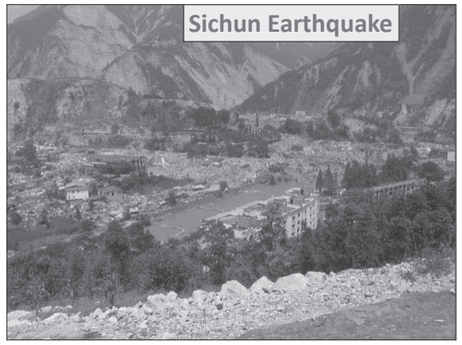
HKICA Certified Internal Auditor
- 1 year audit experience OR
- Existing HKICA internal auditor with 2 years audit experience

中國三峽總工程師　質量就是生命

Sichun Earthquake

Sichun Earthquake

Sichun Earthquake

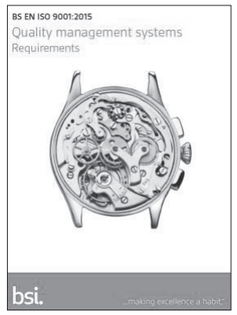


Sichun Earthquake

Florida Hurricane Katrina

Quality Development

- Quality Control: 品質控制 : 1980s
- Quality Assurance : 品質保證 – 1994
- Quality Management :質量 – 2000 & 2008
- Quality Risk Management :質量 – 2015



ISO9001 : Development Background

- 1959: 英國國防部標準 MIL-Q-9858
- 1969: 北約標準系列 NATO AQAP Series of Std
- 1974: BS5179 Guidance
- 1979: BS5750 A Series of Standards
- 1987: ISO9001
- 1994: ISO9001
- 2000: ISO9001
- 2008: ISO9001
- 2015: ISO9001

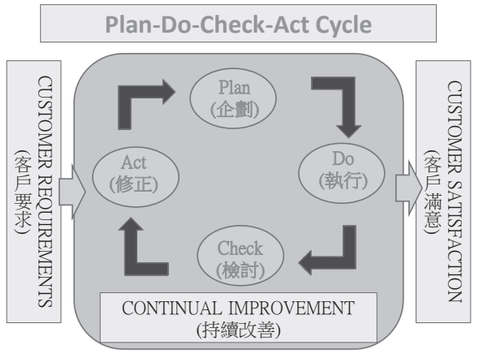
ISO9001:2008 – “4” Elements

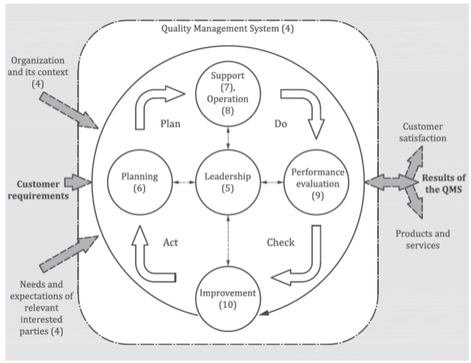
- Management Responsibility (管理職責)
- Resource Management (資源管理)
- Product Realization (產品實現)
- Measurement, analysis and improvement
- (量度, 分析和改善)

ISO9001:2015 – “7” Elements

- Context of the organization
- Leadership
- Planning for the QMS
- Support
- Operation
- Performance evaluation
- Improvement

ISO9001:2015





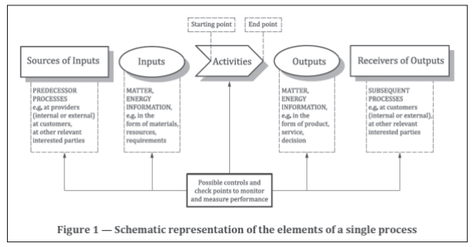


Figure 1 — Schematic representation of the elements of a single process

Where do we meet requirements regarding - "Risks"

- - Determination of the processes taking under consideration risks & opportunity(4.4f)
- - Risks & "opportunity" that can affect conformity of products & services and the ability to enhance customer satisfaction should be determined & addressed (5.1.2b)
- - When planning for the QMS, the organization shall determine the risks & "opportunity" (6.1.1)

Where do we meet requirements regarding - "Risks" (Cont'd)

- - The organization shall plan actions to address risks & "opportunity" (6.1.2)
- - Determining type & extent of control of external provision (8.4.2) –
- be careful, it doesn't use the word "risk", but meaning is that risk is present

Where do we meet requirements regarding - "Risks" 3

- - In determining the extent of post-delivery activities the organization shall consider the risks associated with the products & services (8.5.5a)
- - The management review shall be planned and carried out taking into consideration the effectiveness of actions taken to address risks & opportunities (9.3.1d)

Risk-based thinking (1)

- carrying out preventive action to eliminate potential nonconformities, analysing any NCs that do occur, and taking action to prevent recurrence that is appropriate for the effects of the NC
- needs to plan & implement actions to address "risks and opportunities"
- establishes a basis for increasing the effectiveness of the QMS, achieving improved results and preventing negative effects

Risk-based thinking (2)

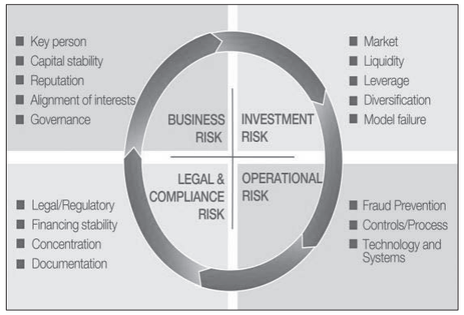
- Opportunities can arise as a result of a situation favourable to achieving an intended result, Example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity.
- Actions to address opportunities can also include consideration of associated risks.
- "Risk" is the effect of **uncertainty** and any such uncertainty can have positive or negative effects.
- A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

Crisis Management Definitions

- Crisis
- In Chinese "wei-ji" = danger & opportunity
- "Decisive moment, Crucial time, Turning point for better or worse"
- "An unstable time or state of affairs in which a decisive change is impeding"
- Crisis Management
- Is the art of "removing" much of the risk & uncertainty from a crisis

Defining Crisis

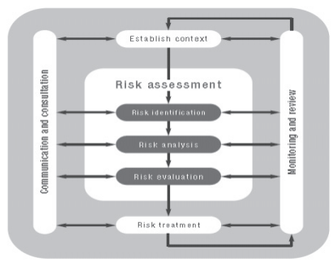
- "Risk" is defined as an "uncertain situation" or an action taken during a prevailing uncertainty when the circumstances or the results of such a situation are unsure of.
- "Risks" are the occurrence likelihood and occurrence consequences of an event
- "Risk" is an effect of uncertainty on objectives (ISO 31000)



Defining Risk Assessment

- Risk Assessment –
- It is defined as set of techniques and methods on the system level to predict future events and their consequences.

Risk Assessment



More about Risk Definition

- Risks are the occurrence likelihood and occurrence consequences of an "event"
- Risk = [(P1, C1), (P2, C2),…….(Pn, Cn)]
- Where:
- Pi = the occurrence **probability** of an outcome of the event and
- Ci = the occurrence consequence of outcomes of the event

More about Risk Definition

- **RISK** = Likelihood x Impact
- **Risk** (Consequence/Time) =
- Likelihood (Event/Time) x Impact (Consequence/Event)
- Note:
- 1. Likelihood can be expressed as a "probability"
- 2. This equation presents risk as an expected value of loss or an average loss

Major Risks – Data from Europe

- National Legislations – 82%
- Environmental Issues – 76%
- **Health & Safety** at work – 72%
- New Technologies – 64%
- **European Legislation** – 50%
- **Political Changes** – 50%
- Society – 36%
- Special Issues – 35%
- **Financial** – 30%
- Legal – 27%

Major Risks – Data from USA

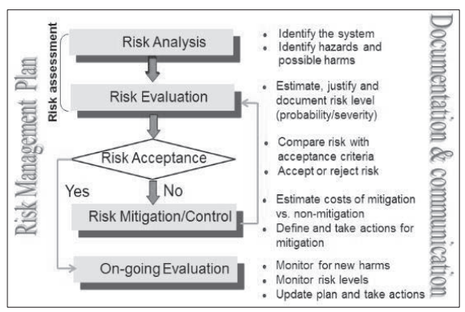
- **Health & Safety** at work – 82%
- **Environmental Issues** – 76%
- Strikes – 72%
- **Products Recall** – 64%
- Ownership changes – 50%
- Control of Corporate Management – 50%
- "Leakage" to Mass Media – 36%
- **State Intervention** – 35%
- **Terrorism** – 30%
- Financial Scandals – 27%

Composite risk index

- **Composite Risk Index =**
- **Impact of risk event X Probability of occurrence**
- The impact of the risk event is commonly assessed on a scale of 1 to 5, where 1 and 5 represent the minimum and maximum possible impact of an occurrence of a risk
- The probability of occurrence is likewise commonly assessed on a scale from 1 to 5, where 1 represents a very low probability of the risk event actually occurring while 5 represents a very high probability of occurrence.
- The composite risk index thus can take values ranging from 1 through 25

Risk options

- Risk mitigation measures are usually formulated according to one or more of the following major risk options, which are:
- Design a **new business** process with adequate built-in risk control and containment measures from the start.
- Periodically re-assess risks that are accepted in ongoing processes as a normal feature of business operations and modify mitigation measures.
- Transfer risks to an **external agency** (e.g. an insurance company)
- Avoid risks altogether (e.g. by **closing down** a particular high-risk business area)



Determine the Consequence

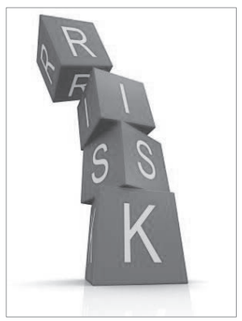
Grading from 1 to 5

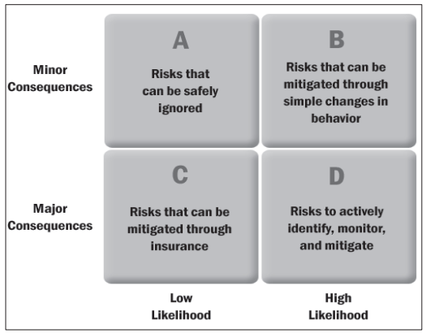
Determine of Likelihood

Grading from 1 to 5

Determine the Risk Rating

Grading from 1 to 25





End of Talk

Risk Management Model		Probability		
		Low	Medium	High
Impact	Severe/Critical	Substantial management required	Must monitor and manage risks	Extensive management crucial
	Moderate	May accept risks but monitor them	Management effort useful	Management effort required
	Limited/Minor	Accept risks	Accept risks but monitor them	Monitor and manage risks

Likelyhood	Consequences				
	Insignificant *Risk is easily mitigated by normal day to day process*	**Minor** *Delays up to 10% of Schedule Additional cost up to 10% of Budget*	**Moderate** *Delays up to 30% of Schedule Additional cost up to 30% of Budget*	**Major** *Delays up to 50% of Schedule Additional cost up to 50% of Budget*	**Catastrophic** *Project abandoned*
Certain *>90% chance*	High	High	Extreme	Extreme	Extreme
Likely *50% - 90% chance*	Moderate	High	High	Extreme	Extreme
Moderate *10% - 50% chance*	Low	Moderate	High	Extreme	Extreme
Unlikely *3% - 10% chance*	Low	Low	Moderate	High	Extreme
Rare *<3% chance*	Low	Low	Moderate	High	High

ISO9001:2015 Challenges and Opportunity for Auditors
Testing, Certification and Risk Management

Mr Tan Yee Chine
TIC Group, SPRING Singapore (Asian Speaker)

Latest QMS Certification Status in Singapore

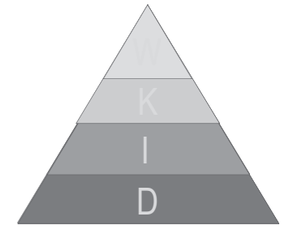
Agenda

- Update on ISO 9001:2015 certification in Singapore
- Analysis of ISO 9001:2015 conversions by TUV SUD PSB
- Challenges for auditors in ISO 9001:2015
- Opportunities for auditors in ISO 9001:2015
- Question and Answer

Interviewing top management on clause 5.1.1

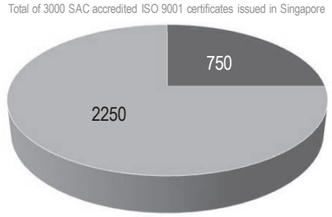
Out of the 10 requirements under clause 5.1.1, how many of these can top management delegate to his/her staff?

Organizational Knowledge



ISO 9001:2015 conversion status in Singapore

Total of 3000 SAC accredited ISO 9001 certificates issued in Singapore



Source: SAC

- No of ISO 9001:2015 certificates issued as of Nov 17
- No of ISO 9001:2015 certificates not issued yet as of Nov 17

ISO 9001:2015 certification by TUV SUD PSB

ISO 9001:2015 conversion status	678 ISO 9001 certificates issued	350 ISO 9001:2015 certificates issued as of Dec 17
51.6 %	ISO 9001:2015 clause numbers for NCs raised eg. 4.1, 4.2, 5.2.2, 6.1, 6.3, 7.1.5.2, 7.2, 7.5, 8.1, 8.3, 8.4.1, 8.5.1, 8.6, 9.2.2, 9.3	

Definition of Risk and Opportunity

Based on the ISO 9000:2015 Vocabulary

3.7.9
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of *information* (3.8.2) related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73:2009, 3.5.1.3) and consequences (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

Note 5 to entry: The word "risk" is sometimes used when there is the possibility of only negative consequences.

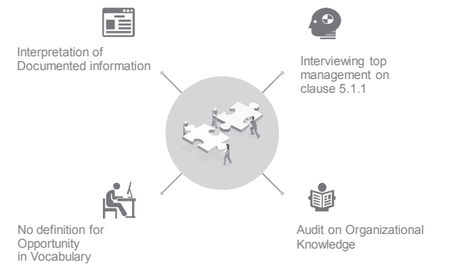
Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 5 to entry.

Definition of Risk and Opportunity

Risk is defined in ISO 9000:2015 Vocabulary

What is the definition of Opportunity ?

Challenges for auditors in ISO 9001:2015



Interviewing top management on clause 5.1.1

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) taking accountability for the effectiveness of the quality management system;
b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
c) ensuring the integration of the quality management system requirements into the organization's business processes;
d) promoting the use of the process approach and risk-based thinking;
e) ensuring that the resources needed for the quality management system are available;
f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
g) ensuring that the quality management system achieves its intended results;
h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Definition of Opportunity

Definition of Opportunity
(from ISO 14004:2016)

- A potential beneficial effect.

An example of Risk and Opportunity

- Using an example from Table A.3 of ISO 14004:2016
- Requirements referred to in Clause 4.2 (Interested Parties) -> Regulator request for information
- Risk = failure to respond, delayed response, or inaccurate response can lead to greater scrutiny from regulatory agency.
- Action plan = develop more effective communication process(es) for receiving and responding to communication from regulatory personnel
- Opportunity = timely, proactive and transparent communication can strengthen the organization's relationship with regulator.
- Action plan = apply internal audit programme to make recommendations to improve timeliness and transparency of communication.

Quality manual and 6 documented procedures of ISO 9001:2008

- Quality manual (Clause 4.2.2)
- Control of documents (Clause 4.2.3)
- Control of records (Clause 4.2.4)
- Control of nonconforming product (Clause 8.3)
- Internal audit (Clause 8.2.2)
- Corrective action (Clause 8.5.2)
- Preventive action (Clause 8.5.3)

Interpretation of Documented Information

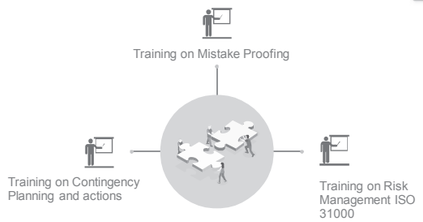
Are these still required under ISO 9001:2015 ?

How many clauses of ISO 9001:2015 require Documented Information to be Maintained ?

Interpretation of Documented Information

- 4.3 Scope
- 4.4.2a To the extent necessary to support the operations of its processes
- 5.2.2 Quality policy
- 6.2.1 Quality objectives
- 8.1.e.1 To the extent necessary to have confidence that the processes have been carried out as planned.
- 8.5.1.a – availability of documented information. Not documented information to be maintained.

Opportunities for auditors in ISO 9001:2015



Mistake Proofing

Is Mistake Proofing a requirement in ISO 9001:2015?

- Clause 8.5.1 (g) the implementation of actions to prevent human error. It is one of the applicable controlled conditions under Production and Service provision

Contingency actions

Is Contingency action a requirement in ISO 9001:2015 ?

- Clause 8.2.1 Customer communication
- Communication with customers shall include 8.2.1(e) establishing specific requirements for contingency actions, when relevant.

Risk Management ISO 31000

To better understand Risk management Principles

To better understand Risk management Framework

To better understand Risk management Process

THANK YOU FOR YOUR ATTENTION

Tan Yee Chine
Principal Facilitator
TUV SUD PSB

PSB Singapore

Choose certainty. Add value.

Mr Thomas Ma
Former Chief Executive, Castco Certification Services Ltd. (Hong Kong)

How to Implement and Enhance Risk-based Thinking in PDCA Cycle

How to implement and enhance Risk-based Thinking in PDCA Cycle ?

Thomas Ma

Purposes to manage Risks

1. To create and protect Value
2. To gain Confidence from stakeholders
3. To prevent or reduce Complaint, Threat, Worries, Illness, Losses, Injury, Death, other Unfavourable matters happened
4. To help improving Brand's Goodwill, Interested Parties' Confidence and Satisfaction, Productivity, Profit, Time, Performance , Compliance, Wellness and Sustained Success

Risk

Type of Risks:

1. Political Risk (World-wide, Nation, Region and Local levels)
2. Legal Liability Risk and Regulatory Compliance Risk
3. Corporate Governance and Boardroom Conflicts
4. Business Risk (Cost Up / Profit Down, Increase of Competitors)
5. Reputation / Brand Risk
6. Threat and Disruption to Business Continuity
7. Disaster (Natural and Human being)
8. Financial / Credit / Cash Flow Risk
9. Market Risk (Expansion, Collapse)
10. Contractual Risk
11. Project Risk, Design Risk, Operational Risk and Technical Risk
12. Cyber Security Risk, Information and Data Risk
13. Health and Safety Risk
14. Environmental Risk
15. Quality Assurance Risk
16. Supplier and Contractor Risk
17. Resource Risk (Staff aging, Lack of skilful labour, High Turnover)
18. Capability Risk (including Human Error)

MTR East Rail disruption caused by failure of both primary and backup servers (11 January 2018)

"The MTR Corporation said the serious service disruption on the East Rail Line today morning during the rush period for about two hours was caused by the failure of both the primary and backup servers of the signaling system, affecting tens of thousands of passengers. .

MTR's head of Operations said around 9am that the signal system encountered a problem as its server was not working smoothly, and the situation did not improve after switching to a backup system.

We had to restart the server manually, but it was not successful. Since the operation needed some time, for safety, the control centre suspended the whole East Rail line around 9:25am,"

14 trains were stuck between stations. Passengers on two trains near the Fanling and Fo Tan stations opened the train doors and walked along the tracks to a station.

A former chair of the Kowloon-Canton Railway Corporation asked -
"Why would a backup server also become unstable?"
"Was it because of maintenance check?"
"Or the procedures need to be improved?"
"Or any other factors, which is what I suspect?"

He continue to question why the MTR changing the signaling system along the East Rail line without stopping daily operations. It may be a factor contributing to this disruption.

"In the history of rail operation in the world as far as I know, there's not been any city or any rail company capable of switching an entire line's signaling system to a new one without temporarily suspending the service.
In Hong Kong we cannot afford to do that."

Risk (Likelihood x Consequence)

Risk Level Classification :

1. Typical Risk level - High High, High, Medium, Low , Low Low
2. Likelihood - (qualitative) Certain, Likely, Possible, Unlikely, Rare; (quantitative) 1 time / 10 cycles , 1 /10000 patients, 1 in every 10 years , 1 in every 100 years
3. Consequence - (qualitative) Disastrous , Significant Loss, Certain Loss, Minor Loss, Insignificant Loss ; (quantitative) > $1 Million , $1 M and > $ 10 K, Lost time 100 ^ mins. ,Recovery time (<10 days)
4. A combination of critical aspects : financial loss , time loss, life loss

Likelihood	Consequences				
	Insignificant	Minor	Moderate	Major	Severe
Almost certain	M	H	H	C	C
Likely	M	M	H	H	C
Possible	L	M	M	H	H
Unlikely	L	M	M	M	H
Rare	L	L	M	M	H

Consequence	Qualitative Descriptors	Quantitative Index	Likelihood: Rare	Unlikely	Possible	Likely	Certain
			< 0.0001	0.001	0.01	0.1	1
	Very High Severity	$0,000,000					
	High Severity	$ 000, 000					
	Medium Severity	$00,000					
	Low Severity	$0,000					
	Very Low Severity	< $000					

INCREASING RISK

Figure 1: Example of a 5x5 risk matrix using log-log quantitative scales.

Risk - Positive / Upside Approach

In most circumstances, risk gives a "Negative or Downside " impression.

Positive Risk Thinking can give us to seek Opportunities:
to protect from losses and harm,
to assure the controls in place
to avoid worst outcomes and negative effects,
to reduce undesirable results.

Challenge of Positive Risk Thinking

1. To see and think a risk differently
   (e.g. weak currency >> more exports)
1. To look at Positive happenings or outcomes, simply arising as a result of actions
   (e.g. Alarm Drill >> enhance the team building spirit and strengthen the co-operation of personnel from different community or functions)
1. To create an unexpected outcome
   (e.g. introduction of flexibility and Partnership approach on Supplier's contract may help reducing costs, improving Customer Services, as well as winning more business.)

Risks can be happened at various levels

National Level

Community Level

Individuals

Security Strategy → Cyber Attack

Shadow Brokers WannaCry Cloudbleed

Health Policy → Flu Explosion

Operation needs → Task Risks

Risk

Definition:

Effect of uncertainty on objectives (ISO 31000:2009)

(Objectives can be financial, business , quality , health, safety, environmental, asset performance and compliance targets)

Effect of uncertainty (ISO 9000:2015)

An effect is a deviation from the expected, can be Positive or Negative (ISO 9000:2015)

Uncertainty is a state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood (ISO 9000:2015)

1. Risk presents naturally in daily life activities, every kind of communication, each decision made, platforms, systems, processes, projects, products, services and assets
2. Risk is typically expressed as a combination of Consequences of an event (including changes in circumstances) and the associated likelihood of occurrence
3. Risk level at different activities, processes, products and services may be different from each other
4. Risk is dynamic, changes with Time, Status and Complexity of Matters.
5. Managing Risk relies mainly on:
   - your individual 's **Common Sense** or your **Organization's Context**,
   - your Attitude or organization's Strategy and Approach ;
   - **Risk Appetite and Risk Treatment** measures ;
   - Resources and Supports available
   - Information, Skill and Knowledge gained as well as **Lesson learnt** !

Risk-based Thinking

- Risk is inherent in all aspects of a QMS, from cradle-to-grave.
- **Risk-based Thinking** gives a power of proactive thinking rather than reactive in preventing or reducing undesired effects through early identification and action.
- By using **Risk-based Thinking** the consideration of risk is Integral.
- **Risk-based Thinking** is something we all do automatically in everyday life
- **Risk-based Thinking** most likely relates to **Common Sense, Awareness and Attention**, associated with Context, Requirements, Knowledge, Technology and Experience
- **Risk-based Thinking** ⟺ **Planned and Unplanned Changes**
- **Risk-based Thinking concept is integrated into ISO 9001:2015 standard:**

Plan-Do-Check-Act (PDCA) Cycle and Process Approach

Risk-based Thinking

- An approach to manage risk, could be systematic,
  - Already part of Process Approach
  - Proactive rather than purely reactive
  - Preventing or reducing undesired effects
  - Embedded preventive action
  - Promoting continual improvement
- Benefits of using risk-based thinking
  - Improve governance and alertness
  - Build a strong knowledge base
  - Establish a proactive culture in your organization
  - Assist with compliances and assure quality of products and services
  - Improve customer confidence and satisfaction

Reference: ISO/TC 176/SC2 /N1222 "Risk" in ISO 9001:2015 and ISO/TC176/SC2/N1269 Risk-Based Thinking in ISO 9001:2015

Risk based Thinking

- Don't forget Risk can appear everywhere and come in a second.
- Don't overlook the multiple Risks and their Impacts
- Don't make any assumption that you are always Safe and Healthy.
- Don't leave your Most Essential things to others, including your Life

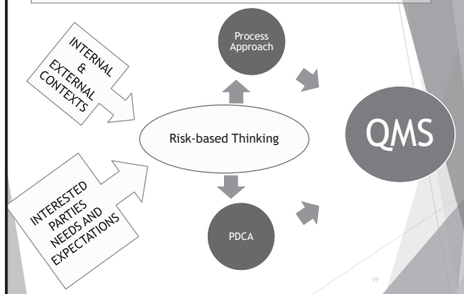
Hong Kong truck driver forgot to lower crane which smashes into overhead footbridge in Shau Kei Wan ! (20 January 2018 news)

Risk-based Thinking

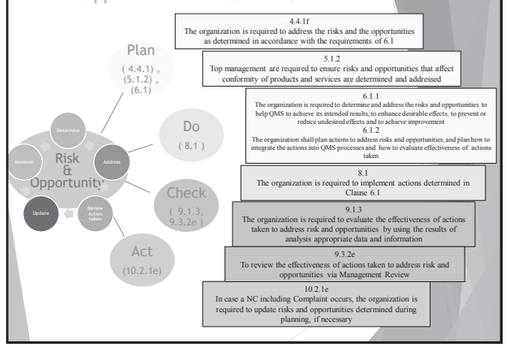
- What to do ?
  - Use risk-based thinking to build up your QMS and Processes
  - Identify what your risks are – it depends on context
  - Different processes have different risk levels
  - Understand what kind of risks that are acceptable, what are unacceptable
  - Plan actions to address, eliminate and treat the risks, then prioritize the risks
  - Take actions according to the Plan
  - Check effectiveness of the actions
  - Learnt from experience, facts, information, context and undesired / adverse effects for improvement
  - Create Opportunity to treat the risk

Reference: ISO/TC 176/SC2 /N1222 "Risk" in ISO 9001:2015 and ISO/TC176/SC2/N1269 Risk-Based Thinking in ISO 9001:2015

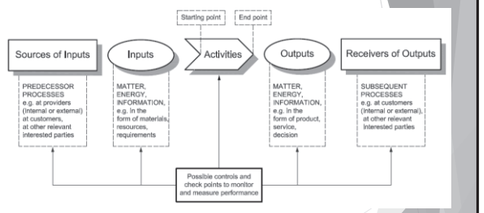
Process Approach, PDCA and Risk-based Thinking



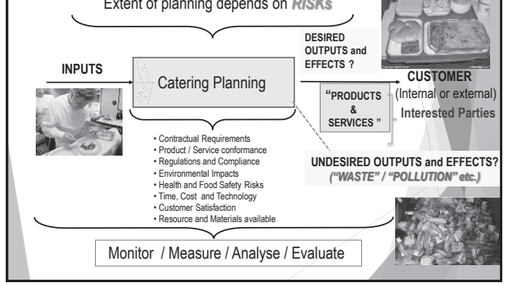
Risks & Opportunities in ISO 9001:2015



Single process model in ISO 9001:2015



Process Approach and Risk-based Thinking



Risks in QMS

Economic benefits that the organization can derive from an investment in a particular Risk Treatment action.

Risk – Lesson Learnt?

Risk with Human Factor ?

Tianjing Explosion Aug. 2015

Taiwan Gas Pipeline Explosion July 2014

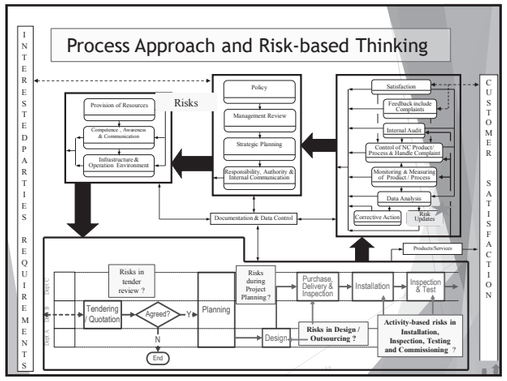
Gas Explosion at Wong Tai Sin, HK April 2015

Likelihood ?
3 similar incidents outbreak in 13 months in same Region

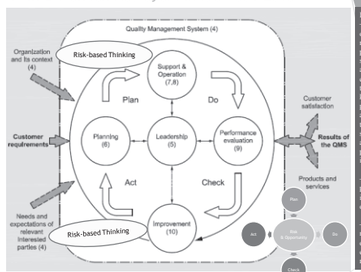
Consequence?
- Numbers of Life lost and wound ?
- Number of family broken,
- Amount of Economic and Property lost ?
-- Recovery Time?

Why no Lesson Learnt?

Process Approach and Risk-based Thinking



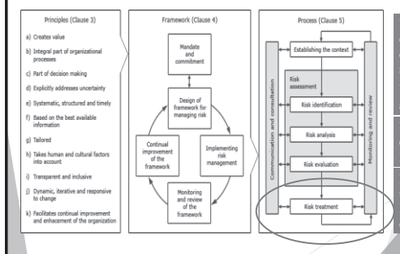
Plan-Do-Check-Act Cycle in ISO 9001:2015



Internal context can include:
— governance, organizational structure, roles and accountabilities; policies, objectives, and the strategies that are in place to achieve them; the capabilities, understood in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies); information systems, information flows and decision-making processes (both formal and informal);
— relationships with, and perceptions and values of, internal stakeholders; the organization's culture;
— standards, guidelines and models adopted by the organization; and form and extent of contractual relationships.

External context can include:
— the cultural, social, political, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local;
— key drivers and trends having impact on the objectives of the organization; and
— relationships with, and perceptions and values of external stakeholders

Risk Treatment in Risk Management (ISO 31000)



What are the expectations and objectives of stakeholders ?

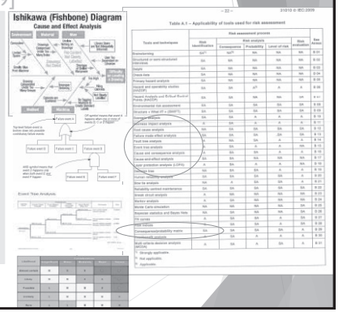
What may happen and why ?

What are the consequences and likelihood ?

How to mitigate or transfer the risk ? Is the controls effective?

Risk assessment tools (typical) [ISO 31010 :2009]

- Cause and Effect Analysis (Fish Bone Diagram)
- Fault Tree Analysis
- Event Tree Analysis
- Consequence / Probability Matrix




THANK
YOU!
I succeed because I manage my risks well !

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