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

Collaborating Organizations

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

CCAA

THE HONG KONG INSTITUTION OF ENGINEERS
香港工程師學會
Control, Automation & Instrumentation Division
控制、自動化及儀器儀表分部

資歷架構
Qualifications Framework

ISO 9001:2015 Challenges and Opportunities for Auditors

Control, Automation, Logistic and Risk Management

Date • 24 May 2018, Thursday

Venue • Regal Riverside Hotel, Shatin (Hong Kong)

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

ISO 9001:2015 Challenges and Opportunities for Auditors Control, Automation, Logistic 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	**Competency of Auditor - International Standard and System**	**Dr Gilbert Gong** Global Personnel Certification Body and IPC Board of Director
10:20 - 11:05	**Development of Certification - Sharing of Taiwan Experience**	**Dr Easter Huang** Chinese National Standard Certification Association (中華國際標準認證驗證協會)
11:05 - 11:25	**Tea Break**	
11:25 - 12:10	**Automation in Food Supply Chain**	**Dr Kit Yuen** N.Law & Associates
12:10 - 12:30	**Discussion and Q & A**	
12:30 - 14:00	**Lunch**	
14:00 - 14:05	**Photo taking with speakers**	
14:05 - 14:50	**Bring the Connected Enterprise to Life: "Automation & IIoT towards Smart Operations"**	**Mr Jeremy Tam** Senior Account Manager, Rockwell Automation Limited
14:50 - 15:35	**Design Risk Management in Semiconductor Assembly Automation**	**Dr Joseph Choy** R&D Director ASM Pacific Technology
15:35 - 15:55	**Tea Break**	
15:55 - 16:40	**System, Competence and Risk Management**	**Ir Dr Tommy Lo** President of Hong Kong Institution of Certified Auditors (Hong Kong)
16:40 - 17:00	**Discussion and Q & A**	

Dr Gilbert Gong
Global Personnel Certification Body and IPC Board of Director

Competency of Auditor - International Standard and System

Competency of Auditor International Standard and System

Dr. Gilbert Gong
Global Personnel Certification

- Why clients expect to be audited by competent auditors?

- Benefits of Auditing from competent audit team

Organizational effectiveness:
- Information for management decisions
- Potential risks identified
- Assessment of resource capabilities (manpower and equipment)
- Identification of cost reduction opportunities
- Maintenance of customer goodwill

Business performance
- Cost control
- Opportunity identification
- Risk management
- Continual improvement

- Benefits of Auditing from competent audit team

Improvement in in system effectiveness:
- Discovery of potential efficiencies in interrelated processes

Improvement in process effectiveness:
- Through examination of interactions with other processes and resources and control utilized

Improvement in performance measurement:
- Provision of timely information to top management
- Facilitation of changes that lead to great effectiveness

Establishing of trusting relationships internally and externally

- Management System Auditing

ISO 19011:2011 defines an audit as a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Audit are independent, unbiased, fact-finding exercises that provide information for decision making

- Principles of Auditing

- Integrity: the foundation of professionalism
- Fair presentation: the obligation to report truthfully and accurately
- Due professional care: the application of diligence and judgement in auditing
- Confidentiality: security of information
- Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions
- Evidence-based approach: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

• Audit

- Audits determine if requirements are being met and if there are opportunities for improvement
- Audits are a prime risk assessment tool
- Audits are indispensable in maintenance and continual improvement of management systems

• Competence in Auditing

- Auditing requires competence (knowledge and skills)
- Certification of auditors is based on relevant training and experience- To be effective, auditors must engage in continual improvement through study and practice

• Competence and Qualification

Conformity assessment –
General requirements for bodies operating certification of persons (ISO/IEC 17024:2012)

- 3.6 competence
  ability to apply knowledge and skills to achieve intended results
- 3.7 qualification
  demonstrated education, training and work experience, where applicable
- 3.8 assessment
  process that evaluates a person's fulfilment of the requirements of the certification scheme

• Competence and Qualification

3.8 assessment

A: Competence based certification:
- the applicant's knowledge, skills, personal attributes and qualifications specific to the program are examined
- emphasize the results of training by assessing competence through valid, reliable and independent examination

B: Qualification based certification:
- relies on an applicant's education and qualifications, rather than on measurable competence
- emphasize training

Terms and definition
- Certification process: Activities by which a certification body determines that a person fulfils certification requirements, including application, assessment, decision on certification, recertification and use of certificates and logos/marks
- Certification scheme: Competence and other requirements related to specific occupational or skilled categories of persons
- Certification requirements: Set of specified requirements, including requirements of the scheme to be fulfilled in order to establish or maintain certification
- Assessment: Process that evaluates a person's fulfilment of the requirements of the certification scheme
- Examination: Mechanism that is part of the assessment which measures a candidate's competence by one or more means, such as written, oral, practical and observational, as defined in the certification scheme
- Fairness: Equal opportunity for success provided to each candidate in the certification process.
- Validity: Evidence that the assessment measures what it is intended to measure, as defined by the certification scheme
- Reliability: Indicator of the extent to which examination scores are consistent across different examination times and locations, different examination forms and different examination teams.

Competence and evaluation of auditors

7.1 General (7 Competence and evaluation of auditors (ISO 19011:2011)

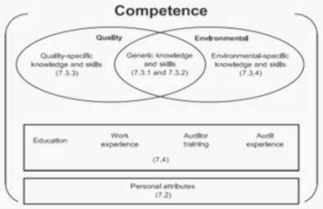
- Confidence in the audit process and the ability to achieve its objectives depends on the competence of those individuals who are involved in planning and conducting audits
- Competence should be evaluated through a process that considers personal behaviour and the ability to apply the knowledge and skills gained through education, work experience, auditor training and audit experience.
- Some of the knowledge and skills described in 7.2.3 are common to auditors of any management system discipline; others are specific to individual management system disciplines
- The evaluation of auditor competence should be planned, implemented and documented in accordance with the audit programme, including its procedures to provide an outcome that is objective, consistent, fair and reliable.

Competence and evaluation of auditors

The evaluation process should include four main steps, as follows:
a) determine the competence of audit personnel to fulfil the needs of the audit programme;
b) establish the evaluation criteria;
c) select the appropriate evaluation method;
d) conduct the evaluation.

ISO 19011:2011 (Guidelines for auditing management Systems) has not provided example of levels of education, work experience, auditor training and audit experience unlike provided in ISO 19011:2002.

Concept of Competence: ISO 19011:2002



- ISO/IEC 17024:2012
- ISO/IEC 17021-1:2015
- ISO/IEC 17021-2:2012
- ISO/IEC 17021-3:2013
- ISO 17000:2004
- ISO 19011:2011
- ISO 29990:2010

International Organization for Standardization

ISO 19011:2002 Audit Experience

Table 1 — Example of levels of education, work experience, auditor training and audit experience for auditors conducting certification or similar audits

Parameter	Auditor	Auditor in both disciplines	Audit team leader
Education	Secondary education (see Note 1)	Same as for auditor	Same as for auditor
Total work experience	5 years (see Note 2)	Same as for auditor	Same as for auditor
Work experience in quality or environmental management field	At least 2 years of the total 5 years	2 years in the second discipline (see Note 3)	Same as for auditor
Auditor training	40 h of audit training	24 h of training in the second discipline (see Note 4)	Same as for auditor
Audit experience	Four complete audits for a total of at least 20 days of audit experience, in the audit-in-training under the direction and guidance of an auditor competent as an audit team leader (see Note 5) The audits should be completed within the last three consecutive years	Three complete audits for a total of at least 15 days of audit experience in the second discipline under the direction and guidance of an auditor competent as an audit team leader in the second discipline (see Note 5) The audits should be completed within the last two consecutive years	Three complete audits for a total of at least 15 days of audit experience, in the audit-in-training in the role of an audit team leader under the direction and guidance of an auditor competent as an audit team leader (see Note 5) The audits should be completed within the last two consecutive years

NOTE 1 Secondary education is that part of the national educational system that comes after the primary or elementary stage, but that is completed prior to entrance to a university or similar educational institution.
NOTE 2 The number of years of work experience may be reduced by 1 year if the person has completed appropriate post-secondary education.
NOTE 3 The work experience in the second discipline may be concurrent with the work experience in the first discipline.
NOTE 4 The training in the second discipline is to acquire knowledge of the relevant standards, laws, regulations, principles, methods and techniques.
NOTE 5 A complete audit is an audit covering all of the steps described in 6.3 to 6.6. The overall audit experience should cover the entire management system standard.

Endorsement of IPC scheme by IAF

IAF MLA Main scopes:

Europe
Body: European co-operation for Accreditation (EA)
Management system certification - ISO/IEC 17021-1
Product certification - ISO/IEC 17065 - 09 Oct 2004
Certifications of persons - ISO/IEC 17024 - 20 Oct 2016

Pacific
Pacific Accreditation Cooperation (PAC)
Management system certification - ISO/IEC 17021-1
Product certification - ISO/IEC 17065 - 09 Oct 2004

Americas
Body: Inter American Accreditation Cooperation (IAAC)
Management system certification - ISO/IEC 17021-1
Product certification - ISO/IEC 17065 - 05 May 2011

Arab Region
Body: ARAB Accreditation Cooperation (ARAC)
Management system certification - ISO/IEC 17021-1

IAF MEMBERS & SIGNATORIES Association Member

IAF MLA

(http://www.iaf.nu/upFiles/IAFIPC_Scan.PDF)

MS Auditor Competences in IPC

Participating Interested Parties:

(http://www.iaf.nu/upFiles/Assessing_Competence_vs_Qualification.pdf)

IPC MLA Full Memember

<http://www.ipcaweb.org/content.aspx?page=119&type=1>

Auditor qualification of FSSC 22000: The process applied to confirm auditor competence.

FOOD SAFETY SYSTEM CERTIFICATION 22000
Part IV: Requirements for Certification Bodies

Annex V – Auditor Competence
1 Purpose
This document states the requirements for certification bodies (CBs) with respect to the auditor competence and qualification process.

2 Scope
These requirements apply to all auditors conducting FSSC 22000 or FSSC 22000 Quality audits – from initial training, through qualification, to requalification and also covers extensions to sector and/or category(ies) and build on the requirements of ISO/IEC 17021-1:2015, ISO/TS 22003:2013 and GFSI BRv7:2017 in this area.

Auditor qualification of FSSC 22000: The process applied to confirm auditor competence.

FOOD SAFETY SYSTEM CERTIFICATION 22000
Part IV: Requirements for Certification Bodies

3 Qualification
There are four steps in the qualification process:
1) selection of the trainee auditor;
2) initial training;
3) witnessed assessment and
4) registration.

3.2 Initial training and experience
The CB shall ensure that trainee auditors are meeting the following initial training and experience requirements:
1) Lead Auditor Course for FSMS or QMS – minimum 40 hours including exam;
2) HACCP training – minimum 16 hours including exam;
3) ISO 22000 Standard – minimum 8 hours including exam (if not included as part of Lead Auditor Training Course);

Auditor qualification of FSSC 22000: The process applied to confirm auditor competence.

FOOD SAFETY SYSTEM CERTIFICATION 22000
Part IV: Requirements for Certification Bodies

3.2 Initial training and experience
4) Food defense training covering food defense risk assessment methodology and possible mitigation measures (including exam);
5) Food fraud training covering food fraud vulnerability assessment methodology and possible mitigation measures (including exam);
6) All relevant Scheme requirements (including exam);ISO/TS 22003 (Annex C), ISO 19011 and ISO/IEC 17021-1 (as applicable to the auditing processes of the CB including exam);
7) Experience in the food or associated industry including at least 2 years full time work in quality assurance or food safety functions in food production or manufacturing, retailing, inspection or enforcement or the equivalent and
8) At least ten 10 audit days and five ISO 22000 or GFSI recognized scheme audits relevant to the specific industry sector including at least one FSSC 22000 audit.

Auditor qualification of FSSC 22000: The process applied to confirm auditor competence.

FSSC 22000

3.3 Assessment
1) The CB shall:
a) provide supervised training in food safety audits;
b) conduct a FSSC 22000 witnessed audit of the auditor to confirm **competence** is attained and
c) document the sign-off of the satisfactory completion of the training program and witnessed audit.

2) The supervised training and the witnessed audit shall be conducted by a FSSC 22000 qualified auditor or an FSSC 22000 technical certification person of equivalent **competence** and experience using the GFSI witnessed audit tool (when available).

IAF MD 9:2017: Application of ISO/IEC 17021-1 in the Field of ISO 13485

7.1 Competence of personnel
Where ISO/IEC 17021-1 Clause 7.1.1 refers to (as relevant for the specific certification scheme) ISO 13485, this should be understood to mean medical devices and applicable legal requirements. All personnel involved in ISO 13485 certification shall meet the competency requirements of Annex B.

7.2 Personnel involved in the certification activities
Each auditor shall have demonstrated competence as defined in Annex C.

MD 7.2.4 Auditor experience
For a first authorization, the auditor shall comply with the following criteria, which shall be demonstrated in audits under guidance and supervision:
a) Have gained experience in the entire process of auditing medical device quality management systems, including review of documentation and risk management of applicable medical devices, parts or services (see Table A.1.7), implementation audit and audit reporting. This experience shall have been gained by participation as a trainee in a minimum of four audits for a total of at least 20 days **in an accredited QMS program, 50% of which shall be against ISO 13485 preferably in an accredited program, and the rest in any other accredited QMS program**.

Table of knowledge and skills

Certification functions / Knowledge and skills	Personnel conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit duration	Personnel reviewing audit reports and making certification decisions	Auditor	Personnel managing program
Knowledge of generic quality management system practices	X	X	X	X
Knowledge of legal framework of regulations and role of the CAB	X	X	X	X
Knowledge of medical device risk management, e.g. ISO 14971	X	X	X	X
Knowledge of intended use of medical devices			X *	
Knowledge of risks associated with the medical device			X *	
Knowledge of relevant product standards in the assessment of medical devices			X *	
Knowledge of CAB's ISO 13485 processes	X	X	X	X
Knowledge of Medical Devicebusiness/technology	X	X	X *	X

* The knowledge in the areas marked with *could be provided by a technical expert.

Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

Parts or services.	Raw materials	Raw metals, plastic, wood, ceramic
	Components	Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic
	Subassemblies	Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions
	Calibration services*	Verification/confirmation services for measuring instruments, tools or test fixtures
	Distribution services	Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices.
	Maintenance services	Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.
	Transportation services	Trucking, shipping, air transportation service in general.
	Other services	Consulting services related to medical devices, packaging services, etc.

*Organizations providing calibration services should be accredited to ISO/IEC 17025

IAF MD 10:2013

IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011

6.3 **Certification in a personnel certification scheme, accredited to ISO/IEC 17024** may be used as demonstrating the competence of personnel, to the extent covered by the scope of the scheme. The AB shall seek evidence that the CB has determined which of its competence criteria are not covered by the scope of the personnel certification scheme and that the CB has performed its own evaluation against these criteria.

6.4 **Where a personnel certification scheme is not accredited** it may be used only as an indication that personnel have certain knowledge and skills, and the **AB shall verify that the CB has performed its own evaluation of competence against the criteria covered by the scheme.**

History of IPC

IPC was established as a non-for profit organization, in 1995, by the name of "International Auditor and Training Certification Association (IATCA)". To adapt to market needs for certification of professionals in a variety of categories, the role and name was changed during the Chicago Annual General Meeting (2003) to "International Personnel Certification Association (IPC)". IPC's main activity is to develop certification schemes for professionals. Although the focus of IPC is personnel certification, recognition of training providers and training courses are also part of IPC's activities. IPC's objective is to promote the interests of our members (personnel certification bodies and other related interest parties) and serve the needs of the society for the competence of professionals. IPC is also a "Scheme owner", which means that IPC develops and owns Certification Schemes (normative documents used for accreditation/certification purposes). These schemes are specifying rules and frames for competence, on which the personnel certification body, member of IPC, may elaborate.

IPC Welcome to IPC, The International Personnel Certification Association. International Benchmark in Personnel Recognition.

IATCA

"IPC MANAGEMENT SYSTEM AUDITORS" IPC-PL-11-006

3.5 Auditing Experience
To be eligible for certification, all auditing experience shall have been gained in the three-year period prior to certification.

3.5.1 Audits for IPC MS Auditor
3.5.1.1
The experience shall comprise the entire audit process from preparation to reporting, in accordance with ISO 19011 or ISO/IEC 17021. This is referred to as a complete audit.
3.5.1.2 The applicant for certification shall have acted as a member of an audit team, team leader or as sole auditor on at least 4 complete audits, the total duration of which shall be a minimum of 20 days including preparation and reporting with a minimum of not less than 8 days on site.

The audits in which the applicant was team leader shall cover the entire audit process from preparation to reporting in accordance with ISO 19011 or the ISO/IEC 17021 family.

First party (internal audits), second party (audit of a supplier) and third party (audit by an independent organization) are acceptable audits.

PREREQUISITES OF IPC MS Auditor

3.1 Education
- Applicants should have completed at least secondary education (typically all the years full-time schooling prior to university entrance).
- Alternative, applicants may be considered for certification (10 years full time work experience and satisfy the PCB that they have achieved a satisfactory level of knowledge for Management Systems auditing.

3.2 Work Experience
- Applicants for all grades with post-secondary education degree shall have at least 4 years full-time (or part time work that totals 4 years) work experience in a technical, professional or management position of accountability involving the exercise of judgement. This period shall be increased to 5 years for applicants with secondary education.
- Applicants shall provide documentary evidence of work experience; this evidence may be presented in the form of employer references giving information on work actually carried out and positions held.
- As an alternative to the documentation requirement in 3.2.2, the applicants can provide a signed self-declaration, giving information on work actually carried out and positions held.

PREREQUISITES OF IPC MS Auditor

3.3 Management System Work Experience
- Applicants shall have a minimum of 2 years relevant experience in the implementation, operation, and/or auditing of management systems, which provides the practical knowledge necessary to audit.

3.4 Training
Applicants shall have completed MS auditor training. The training shall cover the competence required for MS auditors in this scheme. A minimum of forty (40) hours training is required.
Training can be performed by in-class courses, e-learning or other suitable learning methods.
See also IPC-SC-11-002 "IPC Specification on recognition of training courses and training providers".

3.5 Auditing Experience
All auditing experience shall have been gained in the three-year period prior to certification.

PREREQUISITES OF IPC MS Auditor

3.5.1 Audits for IPC MS Auditor
- The totality of auditing experience for auditor grade certification shall be based on requirements of an applicable management system standard as described in annex to this document. The experience shall comprise the entire audit process from preparation to reporting, according to ISO 19011 or ISO/IEC 17021. This is referred to as a complete audit.

- Show as a member of an audit team, team leader or as sole auditor on at least 4 complete audits, the total number shall be a minimum of 20 days with a minimum of not less than 8 days on site.

3.5.2 Audits for IPC MS Lead Auditor

- Lead Auditor grade shall satisfy all auditing and competence evaluation requirements for IPC MS Auditor, and shall have performed as a team leader in at least 3 of the audits required, as described in 3.5.1.2.

The audits in which the applicant was team leader shall cover the entire audit process from preparation to reporting in accordance with ISO 19011 or the ISO/IEC 17021 family. First party (internal audits), second party (audit of a supplier) and third party (audit by an independent organization) are acceptable audits.

PREREQUISITES OF IPC MS Auditor

- SECTION 4 COMPETENCE REQUIRED FOR EACH GRADE OF IPC MANAGEMENT SYSTEMS AUDITORS
- 4.1 Personal behaviour
- 4.1.1. Applicants for certification shall be able to demonstrate the personal behaviour necessary for the effective and efficient performance of the audit as defined in clause 7.2.2 of ISO 19011:2011 and Annex D of ISO 17021:2011.
- 4.2 Competence
- 4.2.1 Knowledge and skills for all Management Systems Auditor grade certification:
- a) Detailed knowledge of ISO 19011
- b) Competence required to fulfil the needs for generic knowledge and skills for management system auditors according to ISO 19011:2011 item 7.2.3.2
- c) How to conduct interviews
- d) How to collect and verify information
- e) How to determine audit findings

PREREQUISITES OF IPC MS Auditor

- f) How to prepare audit conclusions
- g) Types of audits: management system audits, process and product audits;
- h) Principles, procedures and techniques of auditing;
- i) How to relate the auditee management system to the audit criteria;
- j) How to conduct an effective audit in the context of the auditee's organisational situation;
- k) How to evaluate a process approach and process performance;
- l) Regulations, and other specific considerations that are relevant to the management system to be audited;
- m) Personal behaviour necessary for the effective and efficient conduct of a management system audit;
- n) Statistical methods: sampling techniques, basic statistical methods (bar-charts, pie-charts, line-charts and trend-charts);
- o) Audit related risks;
- p) How to communicate effectively with the auditee and audit client;
- q) How to evaluate the procedures common to the other management systems;
- r) How to interpret an integrated management system;

PREREQUISITES OF IPC MS Auditor

- 4.2.2 Knowledge and skills for all Management Systems Lead Auditor grade certification:
- a) All the skills and knowledge listed above for the Management Auditor and
- b) Competence required to fulfil the needs of the audit programme according to ISO 19011:2011 item 7.2.1
- c) Competence required to fulfil the needs to generic knowledge and skills of an audit team leader according to ISO 19011:2011 item 7.2.3.4
- d) How to communicate with senior management;
- e) How to establish, plan and execute the activities of an audit team;
- f) How to organize and direct audit team members;
- g) Conduct the opening and closing meeting
- h) Represent the audit team with audit client and auditee
- i) Provide direction and guidance to team members
- j) Lead the audit team to reach audit conclusions
- k) Prevent and resolve conflicts

PREREQUISITES OF IPC MS Auditor

- l) How to read and evaluate an organization map (organogram);
- m) How to determine appropriate business improvement tools;
- n) How to evaluate the management system effectiveness;
- o) How to prepare and complete the audit report.
- p) How to interpret the financial statements.

7.2.2 Personal behavior in ISO 19011:2011
Auditors should possess the necessary qualities to enable them to act in accordance with the principles of auditing as described in Clause 4. Auditors should exhibit professional behaviour during the performance of audit activities, including being:

— ethical, i.e. fair, truthful, sincere, honest and discreet;
— open-minded, i.e. willing to consider alternative ideas or points of view;
— diplomatic, i.e. tactful in dealing with people;

PREREQUISITES OF IPC MS Auditor

- — observant, i.e. actively observing physical surroundings and activities;
- — perceptive, i.e. aware of and able to understand situations;
- — versatile, i.e. able to readily adapt to different situations;
- — tenacious, i.e. persistent and focused on achieving objectives;
- — decisive, i.e. able to reach timely conclusions based on logical reasoning and analysis;
- — self-reliant, i.e. able to act and function independently whilst interacting effectively with others;
- — acting with fortitude, i.e. able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation;
- — open to improvement, i.e. willing to learn from situations, and striving for better audit results;
- — culturally sensitive, i.e. observant and respectful to the culture of the auditee;
- — collaborative, i.e. effectively interacting with others, including audit team members and the auditee's personnel.

7.4 Selecting the appropriate auditor evaluation method (ISO 19011:2011)

Table 2 — Possible evaluation methods

Evaluation method	Objectives	Examples
Review of records	To verify the background of the auditor	Analysis of records of education, training, employment, professional credentials and audit experience
Feedback	To provide information about how the performance of the auditor is perceived	Surveys, questionnaires, personal references, testimonials, complaints, performance evaluation, peer review
Interview	To evaluate personal behaviour and communication skills, to verify information and test knowledge and to acquire additional information	Personal interviews
Observation	To evaluate personal behaviour and the ability to apply knowledge and skills	Role playing, witnessed audits, on-the-job performance
Testing	To evaluate personal behaviour and knowledge and skills and their application	Oral and written exams, psychometric testing
Post-audit review	To provide information on the auditor performance during the audit activities, identify strengths and weaknesses	Review of the audit report, interviews with the audit team leader, the audit team and, if appropriate, feedback from the auditee

Auditing Management System - General

Competency	Examination methods
Knowledge: • Reference standard: • ISO 19011	1. Written exam
Skills: • Audit preparation; • Audit (on-site); • Audit reporting; • Audit follow-up. All these skills require demonstration of: • Understanding documentation; • Sampling techniques; • Context (religion, culture, social)	1. Live audit 2. Simulated audit 3. Practical activities 4. Written exam
Personal attributes: • Communication (oral and written) • As per ISO 19011 clause 7.2	1. Live audit 2. Simulated audit 3. Oral exam (interview) 4. Written exam

(Referenced from IAF article: Assessing Competence vs Qualification Dr. George I. Anastasopoulos)

THANK YOU

http://www.gpcert.org

Dr Easter Huang
Chinese National Standard Certification Association (中華國際標準認證驗證協會)

Development of Certification - Sharing of Taiwan Experience

DEVELOPMENT OF CERTIFICATE-SHARING OF TAIWAN EXPERIENCE

認證產業分析

第一章 全球認證產業分析

第二章 文獻探討

第三章 結論與建議

畢業典禮

朝陽科技大學
台灣產業策略發展博士學位學程

博士論文

驗證策略對國內生產毛額與對企業風險及品質成本的影響-兼論驗證工作的本質

The Effectiveness of the Certification Strategies to the GDP and to the Enterprises' Risk and Quality Cost: The Nature of Certification

黃立鈞(建岡)博士 Dr. Easter Huang

- 臺灣產業策略發展博士
- 美國密西根大學語言與國貿碩士
- 美國、臺灣、香港及大陸等大專院校教職
- 汽車工作組IATF註冊TS16949資深高級審核員
- 北京海外聯誼會理事
- 中華國際標準驗證驗證協會前理事長
- 美國RAB、德國TUV-CERT及英國SMMT內部見證審核員與發證官Veto
- 前-德國萊茵臺灣區系統驗證部最高主管
- 前NSF-ISR亞太區副總裁-最高主管
- 全國音樂比賽成人組高胡冠軍、京胡冠軍、南胡亞軍
- 20161001出版全球第一本中文書 IATF16949 轉換精要

第一章 全球認證產業分析

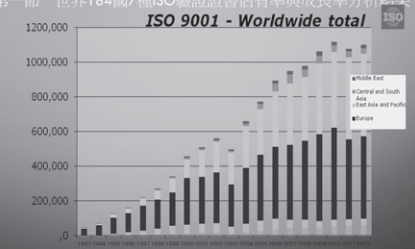
	2016業績 億美元	增長%	稅前利潤	增長	淨利潤	全球員工	分支機搆	備註
SGS 通标	59.85億瑞士法郎(60)	6.0	11.98億瑞士法郎	2.5%	5.86億	90,000	2000	1878年創立於法國法國穀物裝運檢測所
BV 必维	45.5 億歐元 (53)	1.4	8.8	-0.6%		91590	2000	四分之一仍然處於負增長
Intertek天祥	25.67億英鎊 (34.85)	8.8	4.10億英鎊	10.4		27774	1500	產品+ 5.5%，貿易+ 1.3%，資源-13.0%在倫敦證券交易所上市
TÜV南德	23.43億歐元 (27.18)	6	2.02億歐元	6		24000	1500	2016年集團收購資金總額共計1.27億歐元；在西班牙境內完成收購活動：收購ATISAE集團，成爲TUV南德有史以來規模最大的一次收購活動
TÜV萊茵	19.2億歐元 (22.28)	1.9%		6.4%	1.226億歐元	20000	1000	投資規模也繼2015後，再次突破9000萬歐元，達9280萬歐元

全球認證產業分析

- 全球最大的SGS通標認證有限公司。一年高達60億美金，前3大加起來正好是越南一年的GDP=140億美金。
- 檢驗認證行業實際上是，高新技術與規模非常大的企業。
- 例如，德國總理，在訪問中國的時候，一定會去拜訪，德國萊茵。
- 同樣的，法國總統訪問中國的時候，也必定會去訪問最大的認證機構必維BV，他去年的營業額是53億美金，
- 第三名的是，天祥，英國的上市公司，去年是，35億美金。
- 排名四的南德，五的德國萊茵以及七的北德(諾德)營業額超過60億美金以上，
- 全球大型的認證機構都以國家級的檢測機構爲主。 通常都是各國的檢驗機構。例如，排名，第七名的美國UL,這些國家級的檢測機構，通常都附有該國進口產品檢驗的功能與權力。

第四章 實證結果分析與討論

第一節 世界184國7種ISO驗證證書佔有率與成長率分析結果



4-1 The numbers of the ISO9001 certifications for each industry could explain the country 's industrial development.

表 3-12 2012 年 GDP 排名前 45 國 7 種驗證證書與 5 種 GDP 數據表

國家	2012 GDP 百萬美元	2013 GDP	2012 GDP	2013 GDP II	2012 GDP II	ISO 9001	ISO 14001	ISO 50001	ISO 27001	TS 16949	ISO 13485	ISO 22000
美國	15,680,000	16197.96	2.2	51248	49922	26177	5699	3	415	3811	4074	135
中國	8,227,000	9038.66	7.8	6629	6076	334032	91590	3	1490	17975	765	8228
日本	5,964,000	5997.32	2	40442	46736	50339	27774	15	7199	1237	752	762
德國	3,401,000	3373.33	0.7	44010	41513	51809	7034	1115	488	3184	4140	281
法國	2,609,000	2565.62	0	43000	41141	31631	7975	35	71	1039	1129	486
英國	2,441,000	2532.05	0.3	38002	38589	44670	15884	24	1701	567	1573	71
巴西	2,396,000	2503.87	0.9	12291	12079	25791	3300	3	53	1180	127	171
俄羅斯	2,053,000	2109.02	3.4	15650	14247	12491	1090	8	27	194	90	171
義大利	2,014,000	1953.82	-2.4	34034	33115	137390	19705	66	495	1147	2052	820
印度	1,825,000	2117.28	6.6	1592	1492	29402	1034	45	1600	3793	386	1123

10印度已到6 今年超過英 , 8 Russia to 12, Canada to 10, Korea 22 to 15 to 11 ,HK 35 to 40 to 34

加拿大	1,819,000	1839.14	1.8	52364	52232	6907	1778	0	62	478	503	74
澳洲	1,542,000	1598.07	3.6	68939	67723	9185	2000	0	113	143	82	133
西班牙	1,352,000	1311.12	-1.4	30108	29289	59418	19470	120	805	900	260	468
墨西哥	1,177,000	1210.23	3.9	10989	10247	5502	1096	1	75	1121	142	112
韓國	1,156,000	1234.04	2	25051	23113	25706	11479	21	181	4454	212	203
印尼	894,900	1006.89	6.2	3817	3592	5392	1035	0	35	201	22	222
土耳其	794,500	838.973	2.6	11236	10609	7759	1625	1	132	737	86	741
荷蘭	773,100	767.096	-0.9	48091	46142	11417	2085	15	190	133	396	299
沙烏地	727,300	682.583	6.8	25163	25085	2189	185	2	46	0	9	110
瑞士	632,400	616.595	1	80473	79033	11548	2762	14	65	120	843	145

伊朗	548,900	514.821	10	5568	7211	2776	605	9	4	762	65	206
瑞典	526,200	533.94	1.2	60020	55158	4846	3885	72	32	240	266	659
挪威	501,100	520.248	3	105478	99462	1589	824	9	16	16	32	16
波蘭	487,700	496.145	2	13075	12538	10110	2014	10	279	505	193	659
比利時	484,700	475.746	-0.2	45687	43686	3915	1026	16	31	121	143	299
阿根廷	475,000	495.067	1.9	12019	11576	6605	1268	1	33	248	60	108
台灣	474,000	469.287	1.3	21141	20328	8378	2042	37	855	1037	565	321
泰國	365,600	412.711	6.4	6572	5678	8711	3034	41	96	1147	75	235
奧地利	398,600	393.753	0.8	49844	47083	5281	1084	29	28	192	128	68
南非	384,300	402.152	2.5	7257	7507	3918	938	1	22	251	59	218
新加坡	276,500	275.868	1.3	52179	51162	5817	1653	4	65	93	162	108
香港	263,000	273667	1.4	38797	36667	3708	1060	4	110	8	44	73

全球GDP分析

國家	2017 GDP 百萬美元	2016 GDP	GDP 成長率	2016 GDP II	2017 GDP II	ISO 9001	ISO 14001	備註(2012/2013/2016)
中國	12,014,610	11,937,562	7	8123.2	8,643	350631	137230	301040(2)
USA	19,390,600	19,362,129	3	57607	59,501	30474	5582	26177(1)
香港	341,659	334,104	3.5	43561	46,109	2239	684	3701 (HK 35 to 40 to 34)
台灣	579,302	571,453	2	22497	24,577	8889	2171	8738 (26 to 22)
越南	141,669	N/A	7.2	2171.8	1528	5160	1371	6144 (52-46)

中國認證產業分析

	2016業績 (億美元)	增長%	稅前利潤	增長	淨利潤	全球員工	分支機搆	備註
華測檢測 CTI-2003	165,226.07萬元(2.6)	28.30		-43.77%	1.0154億RMB	5000	40	2003成立 營業利潤、利潤總額及淨利潤同比下降 Taiwan Branch loss 20million
國檢集團 CCIC-1998	6.65(億元 RMB(1.05)	2.45	1.50(億元 RMB		1.16(億 RMB	1600 0	300	迄今為止唯一的帶“中國”字頭以“檢驗集團”增長的主要原因是公司不斷開拓市場，拓寬業務範圍
電科院1951 中國電力科學研究院	55,341.03萬 RMB (8733萬)	32.58%	7,720.57萬RMB	309.67		1827	1	規模擴大，同時公司各工程、專案陸續完工結轉固定資產，人員薪酬和折舊費用較去年同期繼續增加，營業成本同比繼續增長；同時管理費用也有所增長，雙聘院士4人擁有博士後流動站1個、一級學科博士點1個，以及電腦應用技術碩士學位點
蘇交科2002	46,379.47萬 (7319萬)	66.39%	43,242.49萬元	5.59%		1700		經營範圍包括工程勘察、設計、施工、試驗、監理及相關技術服務等，公司營業總收入同比增長66.39%，主要是公司合併範圍增加所致（新增並購公司美國Test America Environmental Testing LLC、西班牙 EPTISASERVICIOS DE INGENIER 和中山市水利水電勘測設計諮詢有限公司）
安車檢測	31,818萬元 (5021萬)	12.96	5,855.19萬	16.55%		500		服務全國3000餘家維修企業，1000餘家機動車檢測機構，500餘家大中型運輸企業，100餘個農機監理站所，50餘家汽車製造企業，30餘個城市的行業管理部門，20餘所高等院校，10餘個交通系統的省部級中心站財務良好，

中國認證產業分析

- 中國認證及檢驗產業是在1980年以後才正式開始，目前它的前五大，分別是，華測，國檢，電科院，蘇州交通科學院，安車檢測。五大加起來只有全球最大的SGS通標認證有限公司一年60億美金12分之1=5億美金。
- 中國認證及檢驗產業相對規模都小得很多。營業額也祇有世界最大的百分之一。主要原因是，除了華測CTI,國檢CCIC已經踏出國門，主要是東南亞各國進行檢測，所以有上億美金的營業額。
- 除了，正式上市的五家，其他還有30家以上的新三板上市公司，營業額有的小到祇有幾百萬的人民幣，甚至於2017年可以負成長超過百分之百。
- 由以上結論，如果不踏出中國以外，有他自己專業的檢驗認證也可以在國內取得一席之地且利潤甚至於高達一個資本額，例如，電科院，蘇州交通科學院以及安車檢測。

中國認證上市公司

股票代碼	股票簡称	营业收入	同比增长	净利润	同比增长
		营业额（万元）		额（万元）	
832462	广电计量	56460.30	36.70%	6431.17	54.78%
836325	中检测试	14909.75	16.04%	2314.91	26.58%
300572	安车检测	31818.12	12.96%	4723.19	17.39%
834197	浦公检测	12107.58	18.76%	2935.35	28.67%
831209	鑫安利	12929.12	82.37%	1,633.24	75.50%
836092	乐普基因	10327.15	83.93%	118.29	-65.52%
832172	倍通检测	8329.39	66.46%	1015.13	226.28%
832007	航天检测	7119.73	28.84%	2327.18	69.39%
832462	广电计量	56460.30	36.70%	6431.17	54.78%

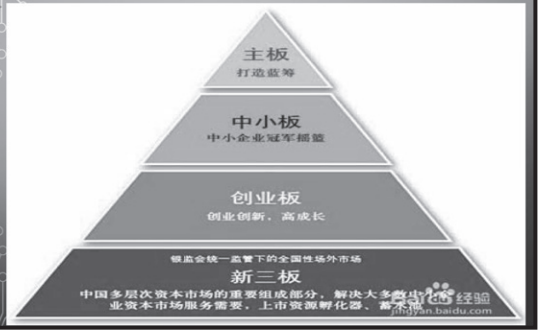
中國認證上市公司

股票代码	股票简称	营业收入	同比增长	净利润	同比增长
		营业额（万元）		额（万元）	
836559	海洞检测	5490.35	44.59%	721.72	48.66%
836944	储融检测	5314.87	40.51%	1308.42	27.83%
835918	瀚海检测	3840.22	84.77%	614.41	115.83%
830846	格林检测	3693.99	78.27%	721.48	54.67 %
835530	逸德汽车	3591.56	73.77%	0.57	-99.20%
839499	西南检测	3534.37	-5.02%	231.17	51.41%
833617	元本检测	3083.34	1.32%	-64.12	-194.93%
834399	贝源检测	3000.13	48.08%	604.61	36.92%
837025	中震检测	2731.05	23.49%	517.95	876.11%

中國認證上市公司

股票代码	股票简称	营业收入	同比增长	净利润	同比增长
		营业额（万元）		额（万元）	
836371	祥源科技	2011.56	13.92%	310.40	-4.43%
831381	中持检测	1981.24	41.29%	201.70	0.16%
830873	奥测世纪	1814.86	44.09%	32.03	-71.33%
870839	普研标准	1823.58	29.19%	-1282.38	-99.17%
837307	环鸿检测	1504.54	32.38%	25.05	35.98%
834445	顶柱检测	1530.63	-15.60%	51.05	-79.79%
835805	华新检测	1110.13	21.98%	44.67	55.09%
834958	华夏检验	1109.78	-8.10%	51.88	-44.15%
832813	瑞博检测	726.82	3.00%	51.90	-

新三板



中國認證產業分析

- 中國認證及檢驗產業是在1980年以後才正式開始，目前它的前五大，分別是，華測，國檢，電科院，蘇州交通科學院，安車檢測。五大加起來只有全球最大的SGS通標認證有限公司一年60億美金12分之1=5億美金。
- 中國認證及檢驗產業相對規模都小得很多。營業額也祇有世界最大的百分之一。主要原因是，除了華測CTI,國檢CCIC已經踏出國門，主要是東南亞各國進行檢測，所以有上億美金的營業額。
- 除了，正式上市的五家，其他還有30家以上的新三板上市公司，營業額有的小到祇有幾百萬的人民幣，甚至於2017年可以負成長超過百分之百。
- 由以上結論，如果不踏出中國以外，有他自己專業的檢驗認證也可以在國內取得一席之地且利潤甚至於高達一個資本額，例如，電科院，蘇州交通科學院以及安車檢測。

發展報告

- 相較於這些國外檢測機構的公司。我國華測跟國檢都不超過20年的歷史，其中國檢16000人，他負責在世界各國進口中國產品的檢測，華測重要的是在國內出口的檢測，所以兩個的營業額分別是2.61跟1億美金，雖然差了一倍，但是利潤都是1億人民幣，甚至於國檢大10%(1.1億人民幣)。
- 首先中國是政策保護，所以全國大型的認證機構都有1億以上的人民幣收入，我們是IAS美國and HKICA-CNAS的認可，如果能夠取得中國的配額。進行海外產品的檢測。主目標是某些領域產品的進口檢測，例如，農產品即食品的部分。同時進行出口產品的檢測與驗證
- 由以上結論，踏出中國，有自己專業的檢驗例如CNC電子產品，車輛檢測(KAPA)。

第二章 文獻探討

第一節 ISO驗證制度歷史之探討
第二節 形式績效指標與實質績效指標兩種假設之探討
第三節 ISO驗證制度與利潤、風險值及質量成本之探討
第四節 ISO驗證的相關實證之探討

2. LITERATURE

- ISO驗證制度是工業發展的火車頭（Fiorenzo Franceschini, 2010）
- 驗證制度的目標是推動與落實國際標準
- ISO的適用價值和領域也受到質疑（Charles J. Corbett, 2001）
- 意大利不同的工商產業別的ISO9001和ISO14000驗證證書張數對國內生產總值GDP的貢獻 (FF 2008)
- 馬來西亞的研究顯示ISO9001與GDP有關(Matthew Potoski, 2013）
- 中國ISO14001卻與GDP無線性關係（A Prakash, 2006）。
- 缺乏對各國整體ISO驗證張數與GDP之研究(Easter Huang,2013）
- G. Cornelis van Kooten 於2012年建議加拿大政府管理森林驗證以推廣經濟；
- 在墨西哥企業獲得第三方ISO驗證可以減少腐敗(Ivan Montiel,2012）

19

2. LITERATURE

- 驗證基本功能包含：一是發揮作爲企業內部管理工具，二是作爲對利益相關者推廣該標準績效的證明。（G.Y.Qi., 2011）
- A. Prakash於2006年提出如果世界主要國家的出口市場都要求自願的ISO驗證證書，對通過驗證的企業貿易量是有關係
- 驗證師檢查船體的情況是否適合海戰或遠航 (Allender,H.D., 1992)
- LR/ABS/CCS/KR/BV/DNV/
- 專業領域的驗證 (黃乃蓮 2004)TUV/BSMI/SGS/NQA/
- 認證機構(Accreadation Board,以下簡稱AB) UKAS/ANAB/CNAB(Hesan A. Quazi, 2004)
- IAF國際認證論壇多邊相互承認協議 (Barry L.M. Mak, 2011)
- S.X. Zeng, 於2005年指出，中國在2002年5月20日成立了該國與全球唯一的認證監管機構「中國國家認證認可監督管理委員會CCAA
- 在使驗證申請者和消費者能夠對驗證機構所提供的檢驗報告及驗證證書建立信心」

20

第三節 名詞詮釋

1. **國際標準化組織**（International Organization of Standard，ISO）：184個國家或區域。
2. ISO國際標準編碼原則：ISO 9001:2008
3. 驗證：依據ISO 9000:2005與我國〈標準法〉第三條:由中立之第三者出具書面證明特定產品、過程或服務能符合規定要求之程序
4. 認證:標準法第三條亦定義認證乃指「主管機關對特定人或特定機關(構)給予正式認可，證明其有能力執行特定工作之程序」。
5. 稽核：系統的、獨立的及文件化的過程以獲取稽核佐證，並客觀地評估之，以決定符合 的界限

A summary of the 2016 results is shown below: TOTAL 1,644,357 1,520,368 +8%

Standard	Number 2016	Number 2015	Change	Change in %	Revenue USA Million
ISO 9001	1106356	1034180	72176	+7%	110(1000)
ISO 14001	346189	319496	26693	+8%	68(2000)
ISO 50001	20216	11985	8231	+69%	10(5000)
ISO 27001	33290	27536	5754	+21%	10(3000)
ISO 22000	32139	32061	78	0	6(2000)
ISO/TS 16949	67358	62944	4414	+7%	33(5000)
ISO 13485	29585	26255	3330	+13%	9(3000)
ISO 223018CM	3853	3133	720	+23%	
ISO 20000-1	4537	2778	1759	+63%	
ISO 28000	356	供應鏈安全			
ISO 39001	478				

第三章 結論與建議

壹、國家ISO驗證本質假設結論

本研究研究結果證實，國家ISO驗證本質『形式績效指標』假設成立

H1假設為全球2012年GDP排名前45國7種ISO驗證證書張數對5種GDP至少有一個顯著影響，研究結果顯示：

H1a成立：2012年各國7種ISO驗證對2012年GDP有正向影響

H1b成立：2012年各國7種ISO驗證對2013年GDP有正向影響

H1cde不成立：2012年各國7種ISO驗證對2012年GDP成長率/2012年及/2013人均GDP/無影響

23

貳、個別企業ISO驗證本質假設結論

一、我國202個別企業2012年ISO驗證本質『形式績效指標』假設結論

H2a成立：2012年企業7種ISO驗證對2012年利潤有影響

H2b成立：2012年企業7種ISO驗證對2012年營業額有影響

H2c成立：年企業7種ISO驗證對2012年風險有影響

H2d成立2012年企業7種ISO驗證對2012年質量成本有影響

本研究發現，個別企業ISO驗證本質『形式績效指標』假設，在樣本母數大於200(我國ISO驗證2%)時成立；

24

控制變項於我國汽車產業限制時不論企業規模大小，企業選擇7種ISO驗證制度對同年利潤、風險及質量成本無差異。

本研究發現，汽車產業ISO驗證本質『形式績效指標』假設不成立；

迴歸方程式(2)

$2012年GDP=139465.1+10.52822X_1-8371.36X_3+383.1194X_4+2787.498X_6$迴歸方程式(4)

$2013GDP=134023.1+12.36946X_1-8734.23X_3+376.0369X_4+2849.97X_6$

25

二、我國汽車產業2012年ISO驗證本質『實質績效指標』

1. 控制變項於我國汽車產業限制時，整體企業與企業規模大於1億企業選擇6種績效指標對同年利潤有差異，可解釋企業51.61%與46%利潤，同理增加到13種績效指標時，可解釋企業62.3%與55.86%利潤，但企業規模小於1億企業選擇13種績效指標對同年利潤無差異。
2. 整體產業企業與企業規模大於1億企業選擇6種績效指標對同年風險值有差異，可解釋企業31.26%與41.56%風險值同理增加到13種績效指標時，可解釋企業34.99%與43.36%風險值，但企業規模小於1億企業選擇13種績效指標對同年風險值無差異。
3. 企業選擇6種績效指標對同年質量成本有差異，整體汽車產業、企業規模大於及小於1億企業各可解釋42.67%、28.09%與46.18%質量成本。同理增加到13種績效指標時，各可解釋48%、35.54%與53.17%質量成本。

研究建議

本研究的首要意義在提出『形式績效指標』與『實質績效指標』兩種假設與相關研究模式，來探討國家與我國產業驗證策略，進而兼論驗證工作的本質。依據研究發現提出以下建議：

國家驗證策略：

1. 本研究模式是建立在控制變項「全球GDP排名前45國」下，以各國7種ISO驗證數對GDP進行分析，控制變項爲已開發、開發中與低開發國家分別瞭解其解釋量變化，以推廣驗證制度與強化該國工業。
2. 控制變項區分成不同工業如重工業，輕工業、基礎工業與服務業的不同國別來研究各國ISO驗證對GDP影響。
3. 本研究結果發現全球GDP前45國SO驗證證書張數可聯合解釋與預測86.3%&74.48%的該國次年GDP與85.9%,75.21%的該國同年GDP，所有資料爲大眾可取得次級資料，信度與再現性極高，各國經濟研究單位可進一步的研究，該國ISO驗證張數是否可預估GDP，或列爲預測因子之一。

27

HK AND TAIWAN AUDITOR FUTURE

- New Item
- Such as 美國 IAS (IAF 會員)認證項目
  FDA/CGAP/ISO9001/ISO14001/ISO45001/ISO13485/ISO27001/ISO22000/2000/39001/
- Product audit such as inspection product safety
- 專業知識：踏出中國，有自己專業的檢驗例如CNC電子產品，車輛檢測(KAPA)。
- 專業具國際資格審核員: 如 HKCIA香港專業審核師學會and Taiwan CNSCA中華國際標準認證驗證協會(CNSCA)

需要資源

- 取得中國的配額。進行海外產品的檢測。例如，電子產品農產品食品的部分。

Training and qualified

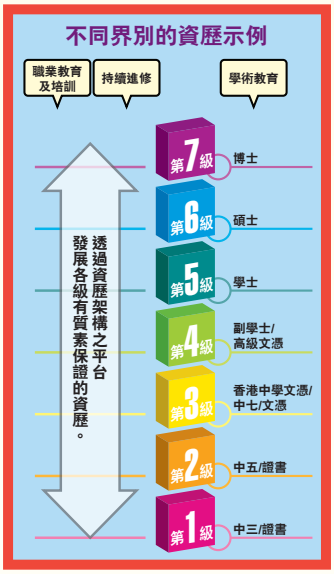
END and QA

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

Membership Pathway of

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

Align with Qualification Framework



HKICA Certified Assistant Auditor

HKICA Certified Internal Auditor

HKICA Certified Assistant Auditor

HKICA Certified Internal Auditor

Passed Examination for Internal / Assistant Auditor

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

Completed HKICA recognized 2-day Internal Auditor Course

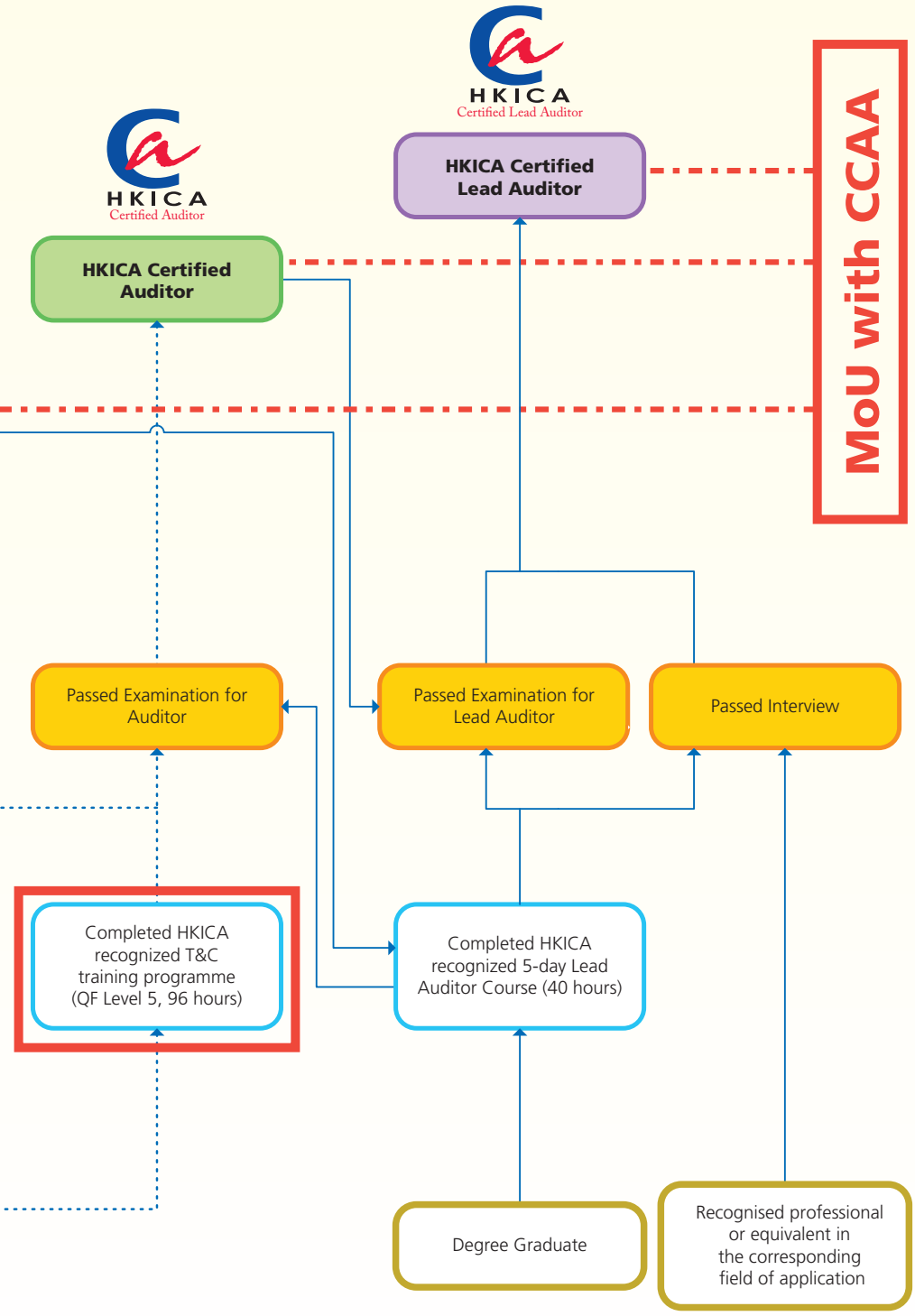
Completed 2-day Internal Auditor Course (by HKICA Lead Auditor)

Existing HKICA Internal Auditor attended 2-day non-recognized Internal Auditor training with at least 2 years audit experience

Other Graduate

HD/AD/Degree Graduate

HKICA Certified Auditors



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

Dr Kit Yuen
N.Law & Associates

Automation in Food Supply Chain

AUTOMATION IN FOOD SUPPLY CHAIN

DR. KIT YUEN

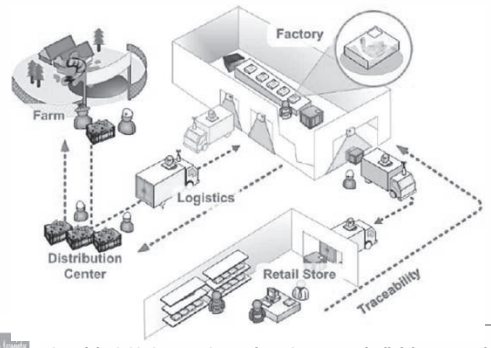
Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

History of Supply Chain in Innovation

1910′ s	Ford Assembly Line	Ocean Shipping Container
1960′ s	Electronic Data Exchange EDI)	Material Requirement planning
1970′ s	Universal Product Code (UPC)	Enterprise Resource Planning
1980′ s	Dell Direct Orders	FedEx Tracking System
	P&G Continuous Replenishment	Walmart Cross Docking
1990′ s	Toyota Production System	HP Postponement
2000′ s	RFID, Track and Trace (Radio Frequency Identification)	Amazon Order and Delivery

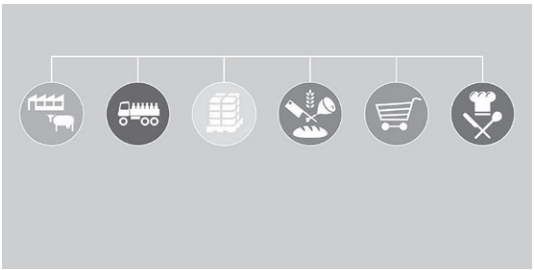
Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Food Supply Chain



Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

FROM FARM TO FORK



Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

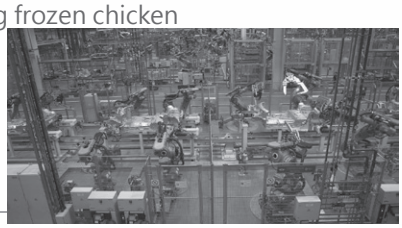
Automating the processing line (1) - Quality

- Safe and Efficiency
- converting lower-paying jobs into higher-paying jobs
- more accurate and precise
- eliminating the ergonomic risks with repetitive motion

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Automating the processing line (2] - OSH

- eliminating the ergonomic risks with repetitive motion
- take over dangerous tasks
- like cutting frozen chicken



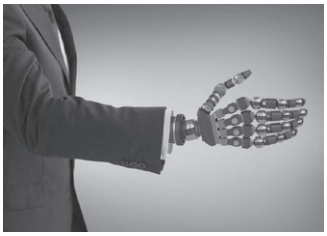
Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Automating the processing line (3) – Food Safety

- can be cleaned with chemicals and hosed down with a water jet
- reduce human contact with the food
- cuts down on *Listeria* and *E. coli* outbreaks
- lost production and sales

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Artificial Intelligence (AI) Automation People



Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

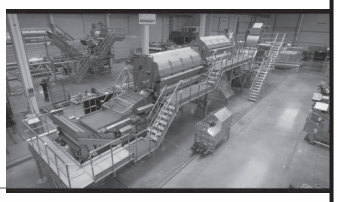
Growing better food

- At the farming level, AI used to detect plant diseases and pests, improve soil health, and more.
- using AI to monitor the effects of variables like UV light, salinity, heat, and water stress
- With the data, developing "recipes" for the perfect crops

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Sorting food

- cameras and near-infrared sensors, to "view food in the same way that consumers do" and sort it based on that perception



Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Ensuring employees follow personal hygiene procedures

- used in restaurants as well as manufacturing facilities
- uses cameras to monitor workers
- employs facial-recognition and object-recognition software
- to determine whether workers are wearing hats and masks as required by food safety law
- If it finds a violation, it extracts the screen images for review

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Managing the supply chain

- Food safety monitoring and testing product at every step of the supply chain
- More accurate forecasting to manage pricing and inventory
- Tracking products from farm to consumer to provide transparency

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Cleaning processing equipment

- uses ultrasonic sensing and optical fluorescence imaging
- to measure food residue and microbial debris in a piece of equipment
- and then optimize the cleaning process.

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

To customers

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

To customers

https://hk.finance.appledaily.com/finance/daily/article/20170401/19976851

給我一個理由朝聖
日本GU神奇自助收銀機

11,446

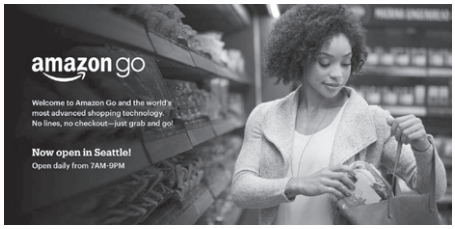
Uniqlo姊妹店GU，已經喺今日正式登陸香港。不過如果你認為，香港人到日本，會從此失去所有到GU朝聖嘅理由？咁又未必，因為有一樣嘢勝，叫「神奇自助收銀機」，係日本GU有，而香港GU未有的。

日本GU早於2015年引入「自助收銀機」，話佢神奇，係有原因嘅。佢家香港一般商店用嘅自助收銀機，都係要大家自己掃貼價碼，逐樣逐樣產品掃，最慘係呀，成日掃唔啱成日都對唔中個Code。不過GU呢部機係，只要你將一堆衫揸入去個「收銀機」嘅入面，（係真係揸入去，你連意擋起放又得，成佢揸入去都得），然後問埋個櫃，一按，佢就半秒左右就自動識別到所有產品，然後你跟住屏幕指示畀錢，跟住走人，閂得！

其實GU都個產品，都喺價錢牌入面嵌入「無線IC標籤」。呢個標籤係採用RFID技術，英文全名Radio Frequency Identification，意思係利用電波（RF）（非接觸式）進行個體識別（ID）嘅「自動識別技術」。正正係RFID嘅善良也，令大家都

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

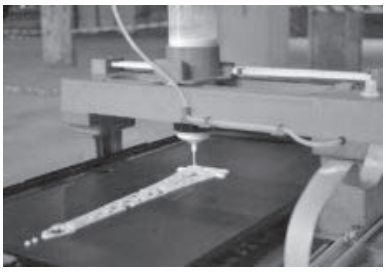
Automating the grocery store?



- https://www.amazon.com/b?node=16008589011&tag=bisafetynet-20

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Future: 3D printing of Food?



Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Risk or opportunities?

Story

Shoe Salesmen in Africa

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Risk or opportunities?

Impact of automation on developing countries puts up to 85% of jobs at risk

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

Risk or opportunities?

Robots and automation: How Africa is at risk

19 March 2018 Share

US companies could move manufacturing operations back home due to falling costs of automation

Within less than two decades it will be cheaper to operate robots in US factories than hire workers in Africa, a new report warns.

Falling automation costs are predicted to cause job losses as manufacturers return to richer economies.

Some analysts say poorer countries could be less impacted by this trend, however the Overseas Development Institute (ODI) suggests otherwise.

But its report adds African nations have time to prepare for the change.

"If done well, automation can present important opportunities for African countries by improving labour productivity in manufacturing," she said.

It has been suggested that poorer countries will not as be affected by automation because they have less money to invest in it.

"Our research shows that this is overly optimistic. Currently the cost of operating robots in furniture manufacturing is still higher than labour, but this will not be the case within 15 years", Dirk Willem te Velde, director of the Supporting Economic Transformation programme at ODI, said in a statement.

ODI's report, **Digitalisation and the Future of Manufacturing in Africa**, found that in furniture manufacturing, the cost of operating robots and 3D printers in the US will be cheaper than Kenyan wages by 2034.

In Ethiopia, ODI predicts robotic automation will be cheaper than Ethiopian workers between 2038 and 2042.

This gives the continent between one to two decades to build up its capabilities in sectors less at risk of automation, "such as food and beverages, garments, metals", the report writes.

It advises African nations to expand access to broadband and develop locals' technical skills through vocational training, technology hubs, and a bigger focus on STEM subjects in African educational bodies.

http://www.bbc.com/news/world-africa-43459138

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

What jobs will disappear because of the ongoing artificial intelligence revolution?

- Transportation. The coming of driverless cars & trucks will require fewer or more specialized drivers.
- Construction & Infrastructure. Ability to better understand the environment will pave the way for more automation of road construction, building robots, and others in the future.
- Logistics & warehousing. There are already robots on the market that can handle these jobs and Amazon has already started using them in its warehouses.
- Manufacturing. Automation has already disrupted this sector and as the degree of automation increases the number of jobs will continue to reduce - machining, assembly, casting, welding, sewing, among others.

Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

5 jobs that AI could replace

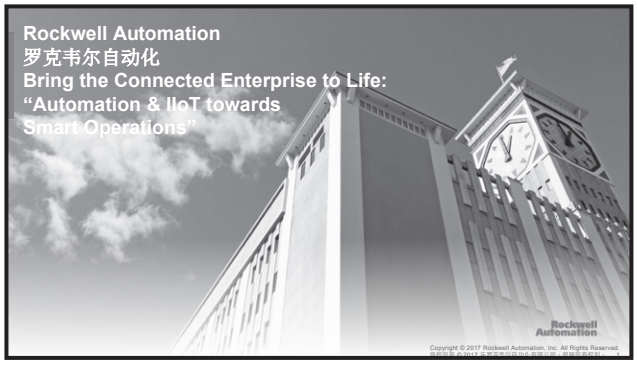
- 1. Personal assistant
- 2. Technical Support
- 3. Drivers
- 4. Factory workers
- 5. Doctor

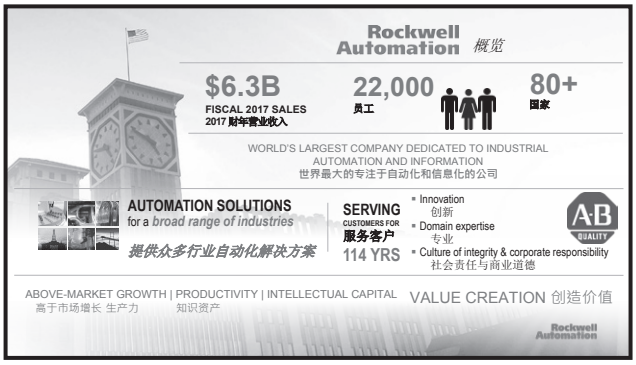
Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

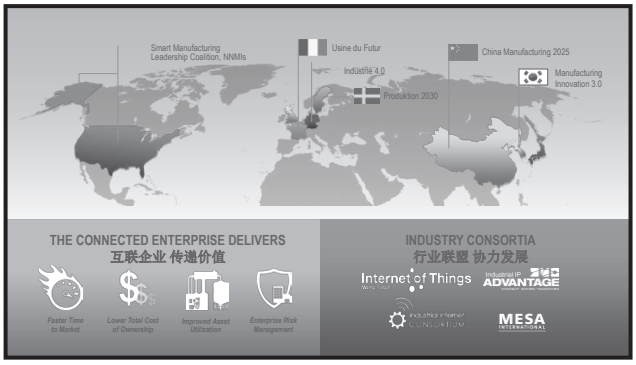
Copyright © 2018 N. Law & Associates Company Ltd. All rights reserved.

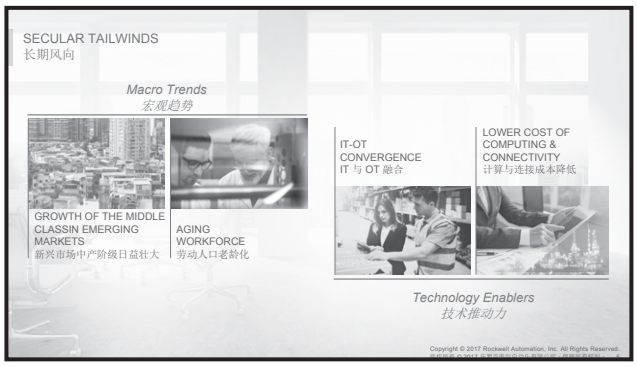
Mr Jeremy Tam
Senior Account Manager, Rockwell Automation Limited

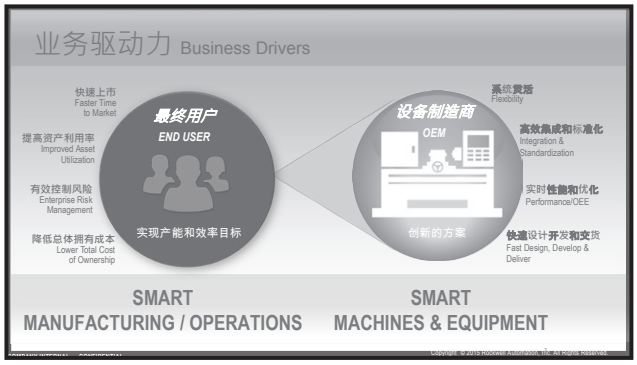
Bring the Connected Enterprise to Life: "Automation & IIoT towards Smart Operations"



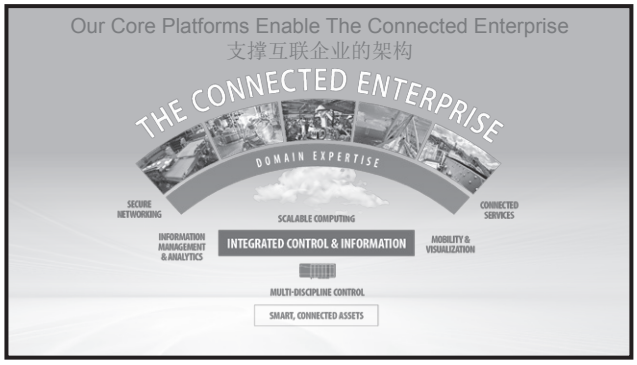


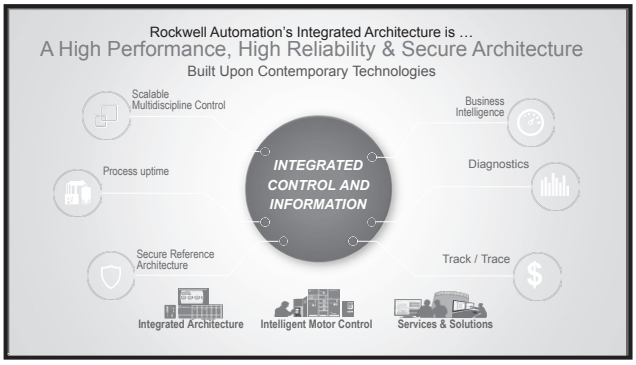


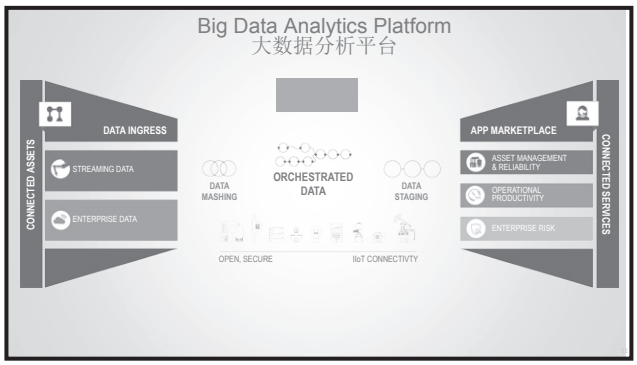


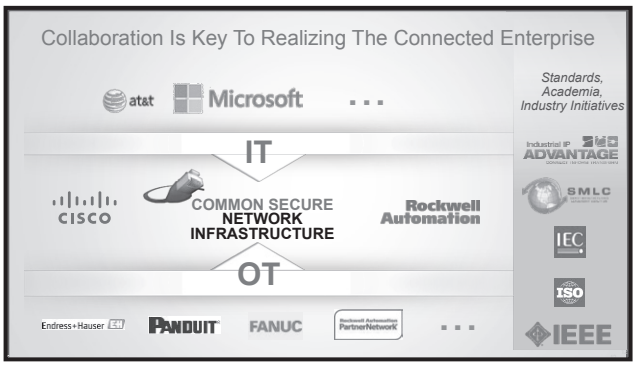

业务驱动力 Business Drivers
快速上市
Faster Time to Market
提高资产利用率
Improved Asset Utilization
有效控制风险
Enterprise Risk Management
降低总体拥有成本
Lower Total Cost of Ownership
最终用户
END USER
实现产能和效率目标
设备制造商
OEM
创新的方案
系统灵活
Flexibility
高效集成和标准化
Integration & Standardization
实时性能和优化
Performance/OEE
快速设计开发和交货
Fast Design, Develop & Deliver
SMART
MANUFACTURING / OPERATIONS
SMART
MACHINES & EQUIPMENT

Bring The Connected Enterprise to Life
互联企业，重在践行
Headquarters
Production
Customers
Smart Grid
Supply Chain
Field-Based Assets
Distribution Center


Our Core Platforms Enable The Connected Enterprise
支撑互联企业的架构
THE CONNECTED ENTERPRISE
DOMAIN EXPERTISE
SECURE NETWORKING
SCALABLE COMPUTING
CONNECTED SERVICES
INFORMATION MANAGEMENT & ANALYTICS
INTEGRATED CONTROL & INFORMATION
MOBILITY & VISUALIZATION
MULTI-DISCIPLINE CONTROL
SMART, CONNECTED ASSETS


Rockwell Automation's Integrated Architecture is …
A High Performance, High Reliability & Secure Architecture
Built Upon Contemporary Technologies
Scalable Multidiscipline Control
Business Intelligence
Process uptime
Diagnostics
INTEGRATED CONTROL AND INFORMATION
Secure Reference Architecture
Track / Trace
Integrated Architecture
Intelligent Motor Control
Services & Solutions


Big Data Analytics Platform
大数据分析平台
CONNECTED ASSETS
DATA INGRESS
STREAMING DATA
ENTERPRISE DATA
DATA MASHING
ORCHESTRATED DATA
DATA STAGING
OPEN, SECURE
IIoT CONNECTIVITY
APP MARKETPLACE
ASSET MANAGEMENT & RELIABILITY
OPERATIONAL PRODUCTIVITY
ENTERPRISE RISK
CONNECTED SERVICES


Collaboration Is Key To Realizing The Connected Enterprise
Standards, Academia, Industry Initiatives
IT
COMMON SECURE NETWORK INFRASTRUCTURE
OT
Rockwell Automation
IEEE

WHY WE WILL WIN
我们成功的理由

- Domain expertise
  领域专业知识
- Large installed base
  庞大的用户群
- Global support
  全球支持
- Secure, standard, open Ethernet
  安全、标准、开放性以太网
- Step-by-step approach
  逐步推进式的方法
- Successful world-class partnerships
  堪称成功典范的合伙伙伴群体
- Wide portfolio of smart plant floor devices
  丰富的智能车间产品组合
- Multi-discipline, scalable architecture
  多策略且支持扩展的架构
- Integrated Control & Information
  集成控制和信息

BEST PEOPLE, PARTNERS AND TECHNOLOGY IN THE INDUSTRY
在业内拥有非凡的人才、合作伙伴与技术

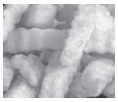
Copyright © 2017 Rockwell Automation, Inc. All Rights Reserved.

SCALABLE ANALYTICS – A KEY DIFFERENTIATOR
可扩展式分析 - 重要竞争优势

	DESCRIPTIVE 描述性	DIAGNOSTIC 诊断	PREDICTIVE 预测性	PRESCRIPTIVE 指导性
ENTERPRISE 企业	Which plant performed the best? 哪处工厂绩效最佳?	Why is Site A throughput behind plan? A 工厂产量为何落后于计划?	I predict that Site A will be behind plan soon. 我预测 A 工厂很快就会落后于计划。	What action should I take to avoid Site A from falling behind plan? 为避免 A 工厂 落后于计划，我应该采取哪些措施?
SYSTEM 系统	Is Line 1 running ok? 生产线 1 是否运行正常?	Why is Line 1 quality poor? 为何生产线 1 的质量低下?	I predict that Line 1 quality is moving out of tolerance. 我预测生产线 1 的质量正在下滑，并将超出可接受的范围。	What action should the operator take to avoid poor quality? 为避免质量低下，操作员应采取哪些措施?
DEVICE 设备	Am I running ok? 运行是否正常?	Why did a fault happen? 为什么会发生故障?	I predict a fault will happen soon. 我预测即将会发生故障。	What action should be taken to avoid the fault? 需要采取哪些措施来避免故障?

Copyright © 2017 Rockwell Automation, Inc. All Rights Reserved.

BRINGING THE CONNECTED ENTERPRISE TO LIFE
让互联企业成为现实
Across a Broad Range of Industries
面向各行各业



CONSUMER
消费品
Industry-leading process optimization and packaging automation solutions
行业领先的过程优化和包装自动化解决方案

TRANSPORTATION
运输
Taking share in powertrain and growing in Electric Vehicles
在动力系统与不断增长的电动汽车领域取得市场

LIFE SCIENCES
生命科学
Fastest growing pharma Manufacturing Execution System (MES) solutions
在制药制造执行系统 (MES) 解决方案领域有理想增速

OIL & GAS, CHEMICAL
石油与天然气、化工
Leader in process safety applications
过程安全应用领域的领导者

MINING & CEMENT
采矿与水泥业
World-class solutions deployable across mining applications
世界范围内知名解决方案，可支持各项采矿应用

Copyright © 2017 Rockwell Automation, Inc. All Rights Reserved.

Copyright © 2017 Rockwell Automation, Inc. All Rights Reserved.

Dr Joseph Choy
R&D Director, ASM Pacific Technology

Design Risk Management in Semiconductor Assembly Automation

ASM Pacific Technology

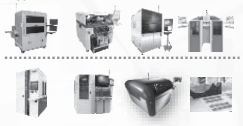
Design Risk Management for Semiconductor Assembly Automation

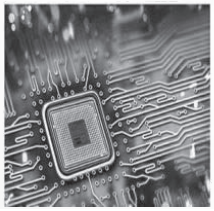
Dr. Joseph Choy
R&D Director
24 May 2018

ASM

A World's Technology & Market Leader

- A leading Integrated solutions provider in the semiconductor assembly, packaging industry and SMT solutions market





Solutions

- Advanced Packaging Solutions
- Copper Bonding Solutions
- Image Sensor Applications
- LED/Opto Solutions
- Smart SMT Factory Solutions
- Display Solutions
- Advanced Fine Pitch Solutions
- Encapsulation Solutions
- Leadframe Solutions
- Low Pin Count & Discrete Applications
- Stacked Die Solutions
- COB Solutions

ASM

Business

Back-end

IC / Discrete — Power Management; IoT

Smartphones; Automotive; Industrial

General Lighting; Display Panel

LED

Dual Camera; 3D Sensing

CIS

SMT Solutions

Strong Europe Market

Industrial

Automotive

China Smartphones

ASM

ASM Pacific Technology
Recognized as TOP 100 Global Tech Leaders

2018 THOMSON REUTERS
TOP100
GLOBAL TECH LEADER

"The Top 100 Global Technology Leaders are the organizations poised to propel the future of technology", Brian Scanlon, Chief Strategy Officer

Thomson Reuters, 2018

ASM

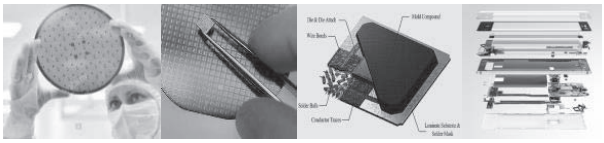
ASMPT Global Presence

> 1,800 global R&D staff
> 1,100 patents on key leading edge technologies
8 R&D centers worldwide
11 manufacturing facilities

ASM

Electronic Packaging Technology

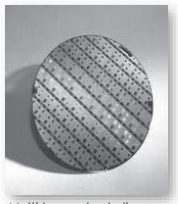
Most of electronic devices operate with silicon chip (IC)

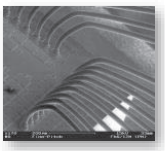


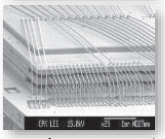
Electronic Packaging & Assembly Workflow

ASM

Precision placement on electronic packages





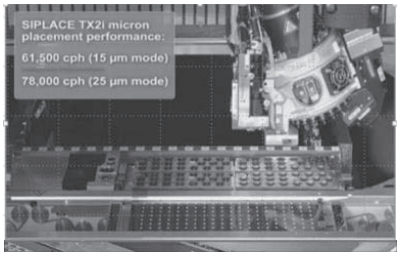


Multi-layers stack die, demands high accuracy, high speed and reliable bonding performance

Every components become smaller for performance and demands high production rate to lower equipment investment costs. The equipment needs to be extremely reliable.

ASM

Highest speed SMT pick & place head (Video)

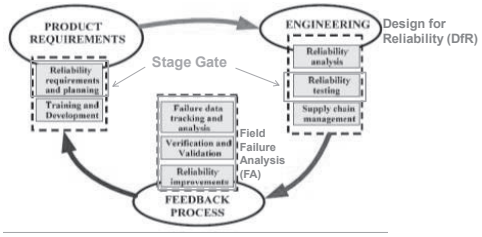


e.g. There are 4 motion travels to pick & place a component, over 1 million cycles per week. Machine design needs to consider both performance and high reliability.

ASM

Reliability system for product development

Our development follows IEEE STD 1624 for Organizational Reliability Capability

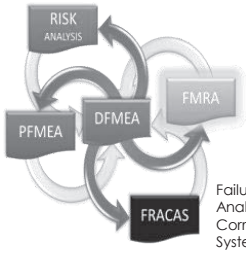


Product life cycle

ASM

Design Risk and Reliability system

- **Some field failure issues are related to design quality**
- **dFMEA, a tool to understand designer's concept & rationale, risk consideration and follow up actions to lower risk,**

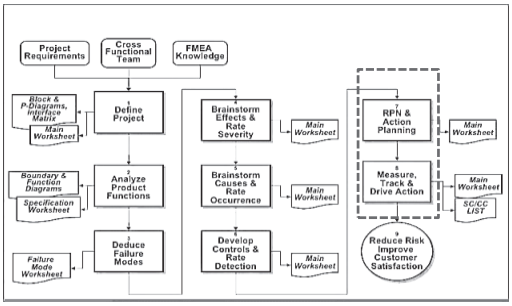


Failure Mode Reliability Analysis (Semi E10)
Equipment Reliability, Availability and Maintainability

Failure Report Analysis and Corrective Action System

ASM

DFMEA Process



The challenge is on execution of risk reduction actions

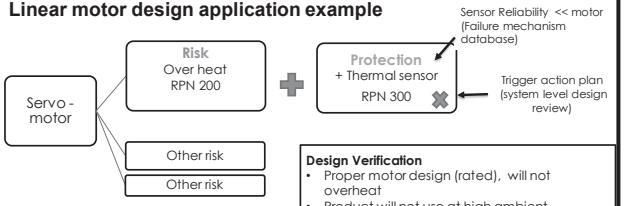
ASM

dFMEA table

Stage 1 defining stage for generic list					Stage 2 brainstorming and discussion stage											
					Reverse Fault Tree type analysis (fill in)		Top-down Fault Tree fail analysis type (fill in)									
Part number	Items	Functions	Stress under Product Life cycle	Potential Failure Mode (total loss function, temporary loss function, degrade ..)	Potential Failure Effect(s) to next higher level	Protection	Severity (S)	Potential Failure Cause and Mechanism from next down stream level	Design Margin	1. Design consideration 2. Past fail occurrence	Occurrence (O)	Validation method used and result for corresponding failure mechanism	Design Validation Levels	Detection (D)	RPN
Z-axis, Rotary Actuator	Provide rotary motion to ball screw, and drive the moving table up and down	1. continuously rotate during motion 2. Stop and brake during idling	Coil burn out if overloaded	1. Totally loss function	1. Limit actuator driving current. Trip the motion axis once overload condition exist		8	N/A	X 2.5	1. Payload and motion requirement of the moving part (Improper actuator selected - overload the actuator 2. Operating current of the actuator (Improper driver current limit - burn out the actuator)	5	1. Burn-in test	1. Follow design rules	5	200

ASM

Linear motor design application example



Design Verification
- Proper motor design (rated), will not overheat
- Product will not use at high ambient temperature
- Magnet strength will not decrease < 110 deg

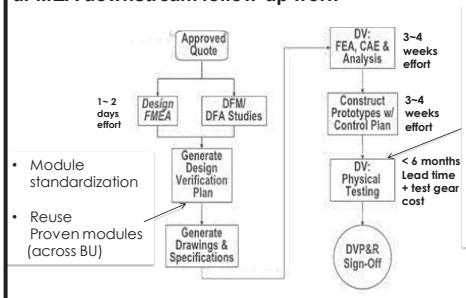
Protection
- Servo system can keep check position error /current limit, use them for temperature monitoring
- Software does not allow user to speed up motor
- No further reliability tests need to carry out

Risk priority number (**RPN**)

= Severity x Occurrence x Detection

ASM

dFMEA downstream follow-up work



- Module standardization
- Reuse Proven modules (across BU)

- Reliability/ Life test take long time
- High speed machine has no room for further speed up life test
- Short development time for customized solution

Significant time and effort can be saved by using dFEMA assessment correctly

ASM

How to sustain a dFMEA practice in an organization ?

ASM

Implementation challenges

- Routine work - can automate by software
- Project / Customer requirement are unique
- Control the process but not kill design innovation

- Roll out DFMEA and easy to complete follow up work
- Share database for failure mode history for FMEA
- Ensure everybody uses the agreed template.

- Ensure the documents are all stored in an easy-to-access database.
- Link between design FMEA and Design verification

- Promote proven module standardization
- Share module library for design reuse
- Execution KPI

ASM

Design Manager - IT platform

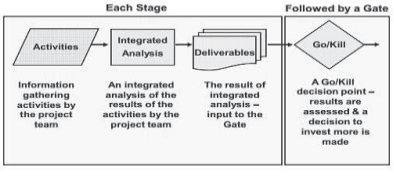
To Integrate: Project magement
Align business units /companies operation by Stage-Gate processes
New product development workflow
R&D & design tool sets
Module reuse & standardization
Information & report automation

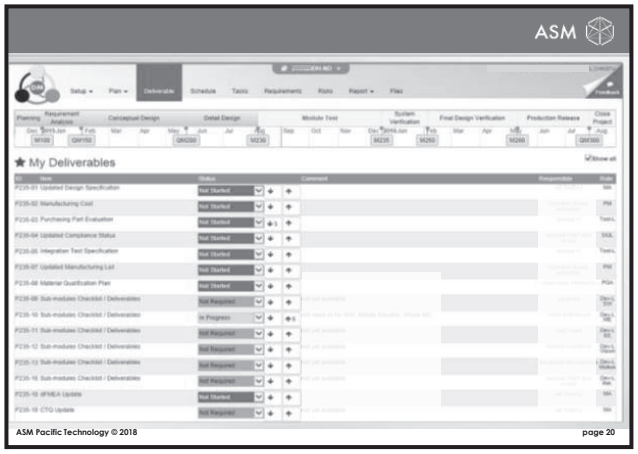
ASM

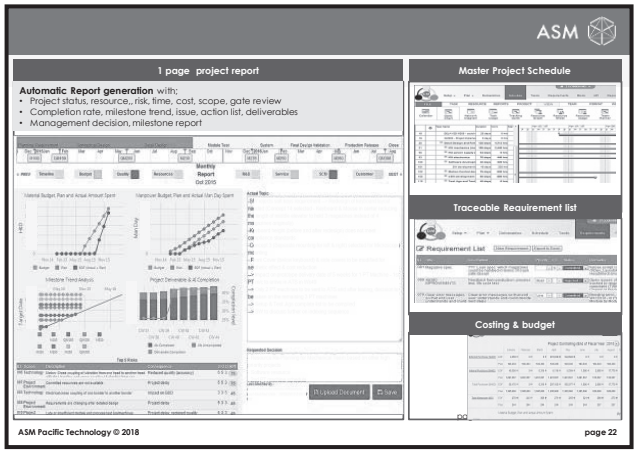
Stage Gate Product Development Process

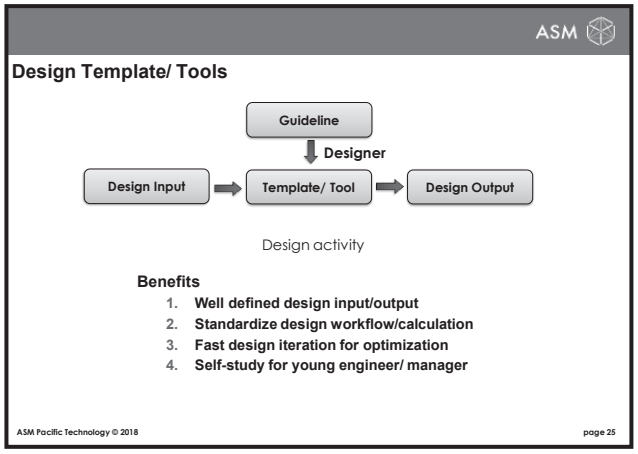
- A project management technique in which project is divided into distinct *stages* separated by decision points known as *gates*

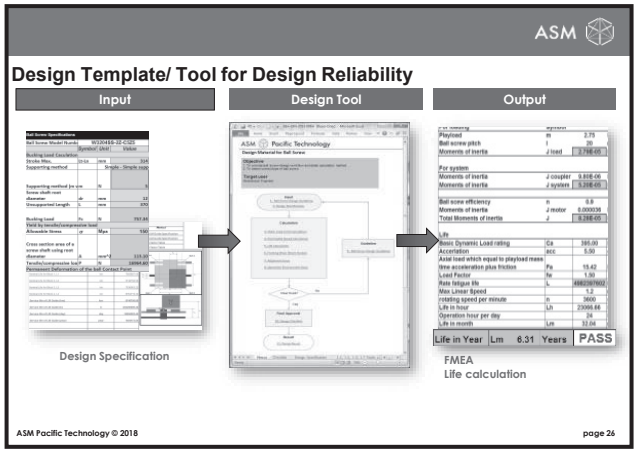
- At each gate, continuation is decided by steering committee, or governance board. The decision is made on forecasts and information available at the time, including the business case, risk analysis, and availability of necessary resources (e.g., money, people with correct competencies).

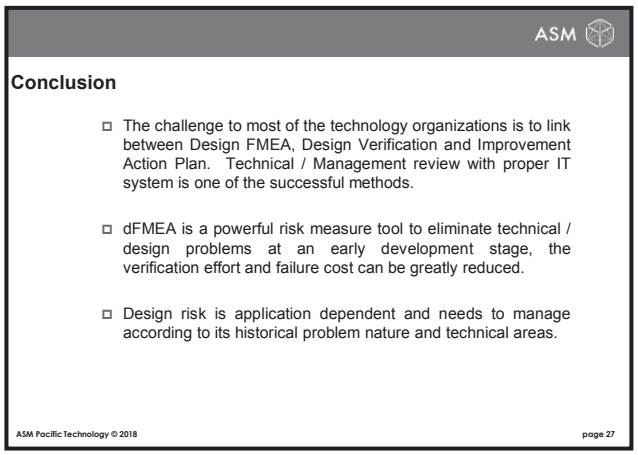


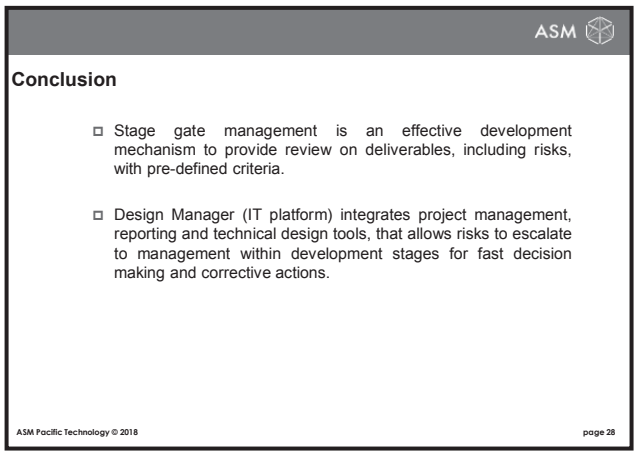

ASM
My Deliverables
ASM Pacific Technology © 2018
page 20


ASM
1 page project report
Automatic Report generation with:
Project status, resource,, risk, time, cost, scope, gate review
Completion rate, milestone trend, issue, action list, deliverables
Management decision, milestone report
Master Project Schedule
Traceable Requirement list
Costing & budget
ASM Pacific Technology © 2018
page 22


ASM
Design Template/ Tools
Guideline
Designer
Design Input
Template/ Tool
Design Output
Design activity
Benefits
1. Well defined design input/output
2. Standardize design workflow/calculation
3. Fast design iteration for optimization
4. Self-study for young engineer/ manager
ASM Pacific Technology © 2018
page 25


ASM
Design Template/ Tool for Design Reliability
Input
Design Tool
Output
Design Specification
FMEA
Life calculation
Life in Year
Lm
6.31
Years
PASS
ASM Pacific Technology © 2018
page 26


ASM
Conclusion
The challenge to most of the technology organizations is to link between Design FMEA, Design Verification and Improvement Action Plan. Technical / Management review with proper IT system is one of the successful methods.
dFMEA is a powerful risk measure tool to eliminate technical / design problems at an early development stage, the verification effort and failure cost can be greatly reduced.
Design risk is application dependent and needs to manage according to its historical problem nature and technical areas.
ASM Pacific Technology © 2018
page 27


ASM
Conclusion
Stage gate management is an effective development mechanism to provide review on deliverables, including risks, with pre-defined criteria.
Design Manager (IT platform) integrates project management, reporting and technical design tools, that allows risks to escalate to management within development stages for fast decision making and corrective actions.
ASM Pacific Technology © 2018
page 28

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

System, Competence and Risk Management

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

Collaborating Organizations :

ISO9001:2015 Challenges and Opportunities for Auditors
Control, Automation, Logistic and Risk Management

审核员的挑战与机遇:控制, 自动化, 物流和风险管理

System, Competence and Risk Management

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

24 May 2018, Regal Riverside Hotel (Hong Kong) 1

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

Introduction

ISO9001:2015 Risk Based Approach

Quality System Risk

Competence of Auditor

Bench marking of Auditor Competence – ISO17024

Who involved in 'Risk management'

ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management 2

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

Introduction

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**;

ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management 3

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

ISO9001:2015 Risk Based Approach

ISO9001:2015

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

ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

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

ISO9001:2015 Risk Based Approach

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)

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

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

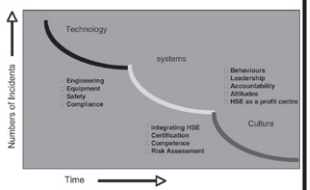
ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

Quality System Risk

Element of success:
Developmental Stages of management System

The Piper Alpha disaster (1988) clearly demonstrated that with the implementation of integrated health, safety and environment management systems, classic safety performance indicators, e.g. fatal accident rate (FAR) had reduced significantly from previous years, BUT none of these indicators reduced to zero.

A plateau was about to be reached after the implementation of the mechanical application of (safety) management systems. Hudson (2007) suggested the developmental line of safety management composed of three stages: technology, system and culture.



The developmental line: culture becomes the next wave after systems

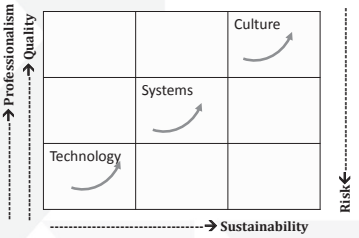
ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

Quality System Risk

Minimize Risk

Auditor:

Impartial System
Competence
Culture



→ Sustainability

Technology (ISO19011)	Ethical (Code of Ethics)	Professional (Incentives (Life long learning))
Guideline CoP	Self Acc System	3rd party Int'l System
ISO19011	Ethical	Professional

ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

Competence of Auditor

FUNDAMENTALS characteristics of auditors

4 Generic competence requirements

The certification body shall define the competence requirements for each certification function as referenced in ISO/IEC 17021:2011, Table A.1. When defining these competence requirements, the certification body shall take into account all the requirements specified in ISO/IEC 17021, as well as those specified in Clauses 5 and 6 of this Technical Specification that are relevant for the QMS technical areas (see ISO/IEC 17021:2011, 7.1.2), as defined by the certification body.

NOTE 1 Annex A provides a summary of the competence requirements for personnel involved in specific certification functions.

NOTE 2 Information on the principles of auditing is provided in ISO 19011.

Competence requirements

Technical requirement

Ethical characteristics (guideline by organization code of ethics)

ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

Competence of Auditor

FUNDAMENTALS characteristics of auditors

ALAN ANDERSON (2012) in her book "**THE CHARACTERISTICS OF A SUCCESSFUL AUDITOR"**

- Strong technical and ethical characteristics to audit success - possess a strong ethical foundation and avoid any temptation to "let it pass"
- A good auditor continues to build upon the career through "commitment to lifelong learning"; maintain appropriate technical skills through required continuing professional education hours.

FUNDAMENTALS characteristics of auditors

- Strong technical **(guideline by ISO19011)** and ethical characteristics (guideline by organization code of ethics) to audit success - possess a strong ethical foundation and avoid any temptation to "let it pass"
- A good auditor continues to build upon the career through "commitment to lifelong learning" **(incentive)**; maintain appropriate technical skills through required continuing **professional** education hours.

ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

Bench marking of Competence

As per ISO 19011:2011, auditors should possess the necessary qualities to enable them to act in accordance with the principles of auditing. Auditors should exhibit professional behavior during the performance of audit activities, including being:

Ethical (i.e. fair, truthful, sincere, honest & discrete)
Open-minded (i.e. willing to consider alternative ideas or points of views)
Diplomatic (i.e. tactful in dealing with people)
Observant (i.e. actively observing physical surroundings & activities)
Perceptive (i.e. aware of & able to understand situations)
Versatile (i.e. able to readily adopt to different situations)
Tenacious (i.e. persistent & focused on achieving objectives)
Decisive (i.e. able to reach timely conclusion based on logical reasoning & analysis)
Self-reliant (i.e. able to act & function independently whilst interacting effectively with others)
Acting with fortitude (i.e. able to act responsibly & ethically, even though these actions may sometimes result in disagreement or confrontation)
Open to improvement (i.e. willing to learn from situations, & striving for better audit results)
Culturally sensitive (i.e. observant & respectful to the culture of the auditee)
Collaborative(i.e. effectively interacting with others, including audit team members & the auditee's personnel)
Communicative, articulate, fluent
Analytical
Patient
Be a good listener

ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

Bench marking of Competence

International Organization for Standardization
Great things happen when the world agrees

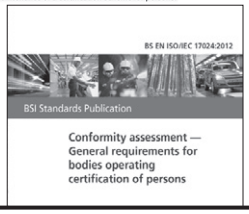
Bench marking of Auditor Competence : Compatible ISO Series - ISO17024

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

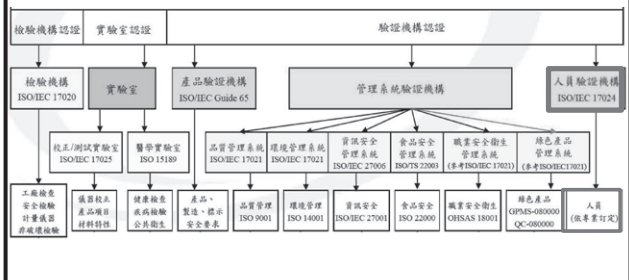
ISO/IEC 17024:2012 contains principles and requirements for a body certifying persons against specific requirements, and includes the development and maintenance of a certification scheme for persons.



Bench marking of Competence

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

Bench marking of Auditor Competence
Personnel Certification Scheme : Compatible ISO Series - ISO17024



ISO9001:2015 Challenges and Opportunity for Auditors
Control, Automation, Logistic and Risk Management

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

Bench marking of Auditor Competence - Personnel Certification Scheme

Compatible ISO Series - ISO17024

Bench marked IAF-IPC MoU

From left to right: George Anastassopoulos (IPC General Secretary), Xiao Jianhua (IAF Chair)

http://www.iaf.nu/articles/IAF_Signs_MLA_Agreement_With_IPC/524

IAF Endorses IPC Management System Auditors Certification Scheme

International Personnel Certification Association's *"IPC Management System Auditors certification scheme"* received endorsement as a sub-scope of the International Accreditation Forum Multilateral Recognition Arrangement (IAF MLA) during the thirty-first IAF General Assembly held on 28 and 30 October 2017 in Vancouver, Canada.

The IPC Management System Auditors certification scheme is the first personnel certification scheme ever to have achieved official endorsement by the IAF. This means more consistency and integrity for Management System Auditors certificates issued around the world.

IPC is only working with those Accreditation Bodies that are participating in the IAF MLA for personnel certification. The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. Certification of persons issued, within the scope of the IAF MLA, by a Personnel Certification Body (PCB) that is accredited by an IAF MLA signatory, ensures worldwide recognition, thereby facilitating international trade.

From now on, the IAF peer evaluation process will take into account not only generic personnel certification requirements, but also the specific IPC scheme normative documents that are now endorsed by the IAF. This creates an additional layer of assurance that ISO/IEC 17024 accredited PCB's – including in their scope the IPC Management System Auditors certification scheme - are certifying competent and knowledgeable management system auditors.

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

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

HKICA Vision (Established in 2006)

- 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）肯建華秘書長頒發

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

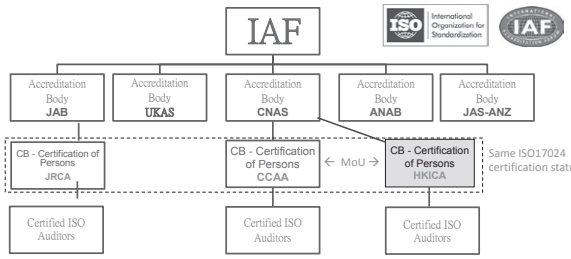
The award ceremony from China National Accreditation Service
to
The Hong Kong Institution of Certified Auditors
June 2016

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 生飛秘書長
August 2016

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.

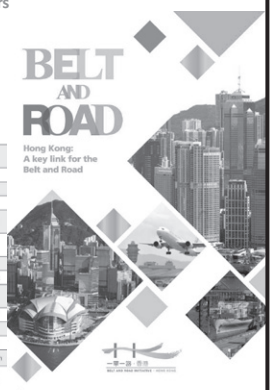
Hong Kong Institution of Certified Auditors
香港專業審核師學會

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	hksasec@hksa.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	hkiplann@netvigator.com
Hong Kong Institute of Landscape Architects (http://www.hkila.com)	852-2896 2833	secretariat@hkila.com

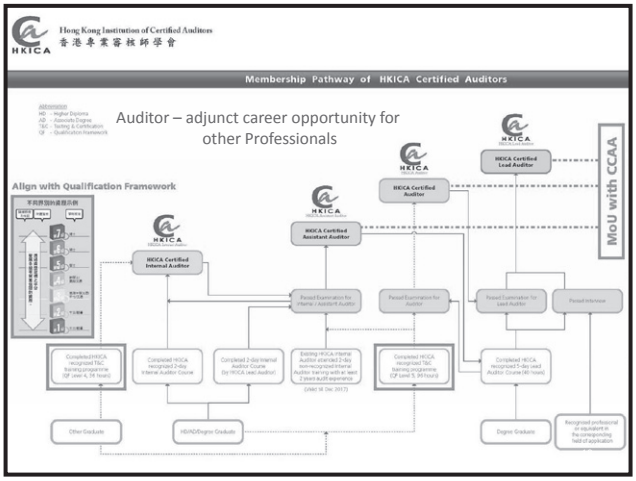


Auditors

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

Membership Pathway of HKICA Certified Auditors

Auditor – adjunct career opportunity for other Professionals



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

国家职业资格目录清单

专业技术人员职业资格（共计58项）

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

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2000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398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2005年第137号） 《注册结构工程师执业资格制度暂行规定》（建设〔1997〕222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	《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2005年第137号） 《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〔2005〕26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〔2003〕27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〕15号）
31	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）
32	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） 《出版专业人员职务试行条例》（职改字〔1986〕第41号） 《出版专业技术人员职业资格考试暂行规定》（人发〔2001〕86号）
33	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37号） 《统计专业技术资格考试暂行规定》（人职发〔1995〕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）

Maintain System Integrity – where to apply

Who involved

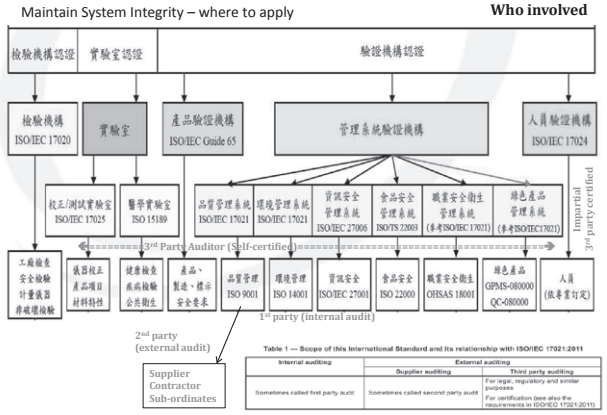


Table 1 — Scope of this International Standard and its relationship with ISO/IEC 17021:2011

Internal auditing	External auditing	
	Supplier auditing	Third party auditing
Sometimes called first party audit	Sometimes called second party audit	For legal, regulatory and similar purposes For certification (see also the requirements in ISO/IEC 17021:2011)

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

Who involved

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.

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

ISO9001:2015 Risk Based Approach

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

ISO9001:2015 Risk Based Approach

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 :

ISO9001:2015 Challenges and Opportunities for Auditors
Control, Automation, Logistic and Risk Management

审核员的挑战与机遇:控制, 自动化, 物流和风险管理

System, Competence and Risk Management

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

website • www.hkica.org

email • info@hkica.org

此刊物／本項目由香港特別行政區政府「專業服務協進支援計劃」撥款資助 。
This material / event is funded by the Professional Services Advancement Support Scheme of the Government of the Hong Kong Special Administrative Region.

在此刊物／本項目的任何活動中提出的任何意見、研究成果、結論或建議，並不代表香港特別行政區政府及專業服務協進支援計劃評審委員會的觀點。
Any opinions, findings, conclusions or recommendations expressed in this material/any event organised under this project do not reflect the views of the Government of the Hong Kong Special Administrative Region or the Vetting Committee of the Professional Services Advancement Support Scheme.

Company Members

CASTCO

FUGRO

BUREAU VERITAS

SGS

DNV·GL

GREEN COUNCIL 環保促進會

Law & Associates

NCF 創業地基 NEW CONCEPTS

科正 建築有限公司 Fraser Construction Company Ltd.

香港公開大學 THE OPEN UNIVERSITY OF HONG KONG
科技學院 School of Science and Technology