

Opportunities for Hong Kong's Auditor Professionals Market Report 2018



**Professionalism is
the Foundation of a System**
Management Commitment towards Quality

ACKNOWLEDGEMENTS

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- China Certification and Accreditation Association
- Standards, Productivity and Innovation Board, Singapore
- Setsco Services Pte Ltd. Singapore
- Taiwan Accreditation Foundation
- Best ISO Certification Co., Limited
- Hong Kong Occupational Safety and Health Association
- Hong Kong Institute of Medical Laboratory Sciences

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FOREWORD

Testing and certification industry is one of the six economic areas identified in 2009 by the Hong Kong Government as having great potential for further development. How Hong Kong Auditors can extend our professional services to different areas and explore global market are key factors contribute to the Hong Kong testing and certification industry.

International Organization for Standardization (ISO) set the minimum threshold requirement on quality product or services which facilitates international trade across boarder. To this end, Hong Kong auditor with its geological advantages are best in providing cross boarder audit and inspection services.

Taking that competency is the international trend in the quality world, competence and professional of internal auditor becomes one of the utmost importance in maintaining the quality system. In Hong Kong, the successful story of Registered Safety Auditor scheme has demonstrated that a well-designed government policy can enhance auditing services and improve the corresponding socioeconomic issues. We believe similar policy addressing competency of QMS auditor will enhance quality culture and releasing market potential for testing and certification trade.

For global market, wide recognition of professional qualification for cross boarder services is one of the key factors to the success. To this end, Hong Kong Auditors' professional status benchmarked to the International Personnel Certification Association (IPC) and having the Mutual Recognition with China Certification and Accreditation Association (CCAA) is a recognition on competency of Hong Kong auditor professional service; the greatness opportunity and key stepping stone for Hong Kong testing and certification industry going global.

This report will provide an overview of Hong Kong and south-east Asia markets in certification industry. It tracks the up-surging needs of management system certifications and their impact on local and global markets. Under globalization and other initiatives such as the Belt and Road, Asian countries are achieving huge gains in market of automobile part manufacturing with the implementation of quality management standard ISO/TS 16949 over the last ten years. In Hong Kong, the demand on services of frontline quality personnel and professional internal auditors for various industries is huge, not only the traditional quality management system (QMS) and environmental management system (EMS), but also some emerging occupational health and safety (OH&S) management system and laboratory management system; there is also a special need on formalize ISO 15189 internal auditor services for maintaining medical laboratory management systems.

I hope this report will be of great interest to QMS personnel and professionals. It provides answers to the key questions: how Hong Kong Auditors can go global and contribute to the Hong Kong testing and certification industry.

Ir Dr Tommy Lo

President

Hong Kong Institution of Certified Auditors

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EXECUTIVE SUMMARY





1. Objectives of the Study and Scope of Report

This market report aims to assess the trends and needs of auditor services (including mainly internal and certification auditors) in Hong Kong, and to evaluate opportunities for auditors in Hong Kong to conduct cross boarder audit and certification in the south-east Asia market. The objectives are summarized as follows:

- reviewed the latest trends, key markets and tracks global progress
- provides answers to how can the testing and certification industry move forwards
- study the areas of service Hong Kong auditor can provide locally and across countries

2. Development of Testing and Certification Trades and Their Market Size

The Hong Kong testing and certification industry has been established for more than 50 years, and grew significantly in 1980s and 1990s. It's also one of the six economic areas identified in 2009 as having good potential for further development. This report will provide an overview to the global market in certification industry.


3. International Trend towards Competency

The word competency is derived from the Latin competere, which means “to be suitable”. Competency of an auditor refers to the ability of an individual to apply his/her knowledge, skills and behaviours to achieve intended results. To ensure effectively implementation of corresponding management system standards, not only certification bodies are required to demonstrate the competence their personnel involved in performing certification functions, but also the auditees have sufficient competent internal auditors and quality assurance personnel. Personnel certification through accredited personnel certification bodies is one of the ways to demonstrate the technical competence of the above-mentioned management system expertise. The Hong Kong Institution of Certified Auditors (HKICA) provided served as a regional hub to provide such personnel certification. With the associations with national and international bodies including the China Certification & Accreditation Association (CCAA) and International Personnel Certification Association, auditors and other management system expertise are recognized widely by certification.

4. Continuous Demand in Local Auditing Services

With the improvement in living standards, there is an increase in awareness not only to the safety and quality of products, but also the adverse environmental impacts caused by the products' manufacturing processes. Renowned retailers required their vendors and suppliers to obtain certifications to quality and environmental management systems, which gives rise to growth in the certification market. Stringent regulations are in place to protect the citizens from safety hazards and minimize the operations of industries in order to reduce the harmful effects on the environment, that also force industries to obtain QMS and EMS certifications. The ISO standards in 9000 and 14000 series specify frameworks for organization to establish, implement, maintain and improve management systems in QMS and EMS respectively, through the use of plan-do-check-act (PDCA) approach. The certification of QMS and EMS will remain to be the major contributors in the certification industry, which will create continuous job opportunities for auditing services within the local and south-east Asia markets.

According to recent statistics by the Hong Kong Labour Department, there were 11,077 and 35,631 cases of industrial accidents and occupational injuries respectively in 2017, where there were 256 fatalities among these cases. Although most of the cases were non-fatal work-related injuries and



accidents, they would still lead to substantial loss by organizations due to absences from work. Besides, the United Nations agency estimating the occupational illnesses, injuries and deaths costs a total of 3.94% of the global gross domestic product (GDP), which equivalent to USD 2.99 trillion. The launching of new standard ISO 45001 “Occupational health and safety management systems -- Requirements with guidance for use” in 2018 provided an opportunity to the Hong Kong certification industry to increase the share of market and the demand of auditors and OH&S management system expertise.

Similarly, the latest update of the ISO/IEC 17025: 2017, the demands in competence of these personnel for laboratories have been increased in order to deal with the new “goal-setting” approach and other new requirements (such as risk-based thinking).

The demands of auditors and quality assurance expertise of these standards will foreseeable be increased, which create more career opportunities internally

5. Demand in Frontline Quality Professional / Internal Auditor Services

Management system without “Professional Man” will not be a sustainable management system. To maintain an effective and high quality QMS, 97% of the Manpower Demand for audit services is internal auditor and frontline QA personnel to deal with daily management system maintenance, internal audit and other quality assurance activities. The demands for effective training and personnel certification are expected to be high.


6. Global Opportunity: Development of ISO16949: Automobile Parts in Asian Market

Based on the survey conducted during the visits to Taipei, Singapore and Beijing by members of HKICA, two emerging system certifications have been identified to have potential for development in the south-east Asia. The first one refers to IATF 16949:2016 “Quality management system requirements for automotive production and relevant service parts organizations” published by the International Automotive Task Force (IATF), which has superseded and replaced technical specification ISO/TS 16949: 2009. This standard establishes detailed requirements concerning the quality management system during the production process as well as assembling and maintenance of products connected with the automotive industry, and requires to be used in conjunction with ISO 9001: 2015. According to the data from the ISO Survey of Management System Standard Certifications, the total number of ISO/TS 16949 certificates in Hong Kong, China, Taipei and Korea were increased dramatically from less than 1,000 pcs in 2004 to 35,572 pcs in 2016. With the latest upgrade of the technical specification to IATF 16949 Standard, IATF requires authorized certification bodies (around 42 certification bodies as of October 2018) to conduct IATF 16949: 2016 certification activities. We would foresee a huge demands of competence auditors for certification, second party auditors, internal auditors as well as quality assurance personnel to cope with the automotive parts production industry.

7. New Market Potential: ISO15189 Internal Auditor Services

The second system certifications have been identified to have potential for development globally refers to ISO 15189:2012 “Medical laboratories – requirements for quality and competence”.

Early before 2004, Hong Kong medical laboratories seek ISO15189 accreditation from overseas such as National Association of Testing Authorities (NATA) or College of American Pathologists (CAP). The subsequent HKAS accreditation is also based on ISO15189. Over the year, the ISO15189 scheme is not well supported by appropriate trained internal auditors though there is demand that the training



and qualification of each position including internal auditor appointments, to be appropriate to the tasks performed. Current supply of internal auditors are trained in other inequivalent schemes, such as ISO 9001:2015 entitled 'Quality management systems and ISO/IEC 17025:2017 entitled 'General requirements for the competence of testing and calibration laboratories'. Similar situation also happened in many countries worldwide. Accordingly, there is an ample need on ISO 15189 trained personnel to conduct internal audits of medical laboratories that have been accredited to ISO 15189:2012.

8. Leading Edge of Hong Kong Certified Auditors

With the feedbacks received from the visits to Taipei, Singapore and Beijing by members of HKICA, we have considered certified auditors in Hong Kong having the following strengths:

Recognition of the competence. Certification of QMS auditors by HKICA is accredited in accordance with ISO/IEC 17024 "General requirements for bodies operating certification of persons", where HKICA has strong association with various national and international personnel certification bodies including CCAA and IPCA and facilitate the recognition of HKICA's certification status.

Proximity of Hong Kong to the Mainland, Taiwan and other parts of south-east Asia. South-east Asia is one of the major manufacturing centers worldwide. Hong Kong certified auditors can provide fast response and support to the audit services for manufacturers in the south-east Asia region.

High integrity and good intellectual property. A high credibility of the Hong Kong certified auditors give confidence to clients to conduct their audit services in impartial manner.

Good language and communication skills. Proficiency in English and Chinese made Hong Kong certified auditors can conduct their audits smoothly in various geographical locations of the south-east Asia region.

Leadership with international lifestyle. Due to special historical situations, Hong Kong people in general developed an international lifestyle which are diplomatic and adaptive to different environments

Higher work efficiency. Hong Kong people used to work in a fast-paced environment, which lead a higher efficiency for the certified auditors during their auditing services.

Higher education level. According to the 2016 data from the Hong Kong Census and Statistics Department, 32.7% of Hong Kong population aged 15 and over have attended post-secondary education, where 70% of professional staff in the testing and certification industry are degree holder or even postgraduate.

Chapter 2: **Development of Testing and Certification Trades and Their Market Size**



Development History

Hong Kong's certification industry started to develop in the late 1980s as the first edition of the emerging quality management system standard, ISO 9000, was published in 1987. The first certification body in Hong Kong was set up in 1989 and several international certification bodies to assist local industry and commerce to develop and practice quality management systems. The number of ISO 9000 certificates has dramatically increased since 2001, after the Works Bureau of the HKSAR Government published a technical circular (WBTC No. 4/2000) in which contracts inviting tenders on or after June 2000 required contractors to obtain ISO 9000 quality management system certifications.

In addition to ISO 9001 certification, certification bodies in Hong Kong also provides other kinds of management systems certification, including certification for ISO 14001 environmental management systems, OHSAS 18001 occupational health and safety management systems (note that this will be replaced by ISO 45001), ISO 22000 food safety management systems, ISO/IEC 27001 information security management systems, ISO 50001 energy management system, etc.

Global Certification Market


According to the global testing, inspection, and certification (TIC) trends and prospects analysis by Barclays in 2018, the largest three players in TIC market, namely SGS (Switzerland), Bureau Veritas (France) and Intertek (UK), hold a combined share of 25 % of the whole market. This reflects a highly specialized by discrete market in TIC industry, where the global TIC market is valued at around US\$230 billion. Several factors such as harmonization of standards, growing consumption of goods in emerging countries, increasing incidents of product recalls, surge in global counterfeiting and piracy activities, and imposition of rigorous government regulations and standards across various sectors, lead to a strong driving force of the TIC market.

According to the survey conducted by the International Organization for Standardization (ISO) in 2016, the total number of major ISO certificates worldwide were summarized in Table 1, where 1.64M of certificates were issued according to ISO 9001, ISO 14001, ISO 50001, ISO 27001, ISO 22000, ISO/TS 16949 and ISO 13485 Quality management systems for medical devices.

Table 1: Summary of different types of ISO certificates worldwide (2016)

Management system	Number of Certificate
ISO 9001	1,106,356
ISO 14001	346,189
ISO 50001	20,216
ISO 27001	33,290
ISO 22000	32,139
ISO/TS 16949	67,358
ISO 13485	29,585

The global certification market is experiencing growth owing to the factors such as increased outsourcing of services and diversified requirements of products and standard regulations. Regulations pertaining to quality, environment, health and safety have become more stringent in the recent years also drive an increase in the demand for certification services. Besides, buyers and even consumers believe third-party assurance improved the quality of products and minimize the risk also contribute the use of certification services worldwide.



In Asia, the number of ISO 9001 certificates takes 36% of the global business need and ISO 9001 and ISO 14001 certificates are of greatest demand. The number of ISO 9001 and ISO 14001 certificates is 397,393 and 147,038 respectively (Table 2).

Based on a study by Potoski et. al. (2009) relating to ISO 9000 and international commercial, there is statistically significant and positive coefficients for the use of ISO 9000 series certification in developing countries to increase exports. As exports are blooming in many of the countries in south-east Asia, we will foresee the number of management system certificates and the relevant audit services will continue to grow.


Table 2: Status of ISO 9001 and ISO14001 certificates of Asian country (2016)

Economic Zone	2017 GDP (million USD)	ISO 9001	ISO 14001
Mainland, China	12,014,610	350,631	137,230
Hong Kong	341,659	2,239	684
Taiwan, China	579,302	8,889	2,171
Vietnam	141,669	5,160	1,371

Chapter 3

International Trend Towards Competency - ISO 17024 Certification System of Persons





Personnel certification is a status symbol for competent auditors. According to the Mandatory Document (MD) No. 10 issued by the International Accreditation Forum (IAF) regarding assessment of certification body management of competence, obtaining personnel certification according to ISO/IEC 17024 may be used to demonstrate the competence of personnel.

Over the years, there is an emerging trend for personnel certification body offering competence-based certification scheme to examine auditor's knowledge, skills, personal attributes, and qualifications specific to the program and/or scope of certification. Beforehand, some organization offered a similar qualification-based "registration" scheme, which relies on applicant's education and qualifications, rather than assessment by means of measurable competence. A typical example to illustrate the difference is a person who has newly acquired a driving license (qualification) but he/she doesn't have any confidence to drive a car in the street (competence).

ISO 17024 Certification System of Persons – Signatory of Competency

To ensure the assessment of competence instead of qualification, ISO has published ISO/IEC Standard 17024 Conformity Assessment – General requirements for bodies operating certification of persons, which explicitly specified certification of persons by means of demonstration of competencies. By using ISO/IEC 17024, certification industry can recognize auditors through personnel certification.

The International Personnel Certification Association (IPC) launched its "IPC Management System Auditors Certification Scheme" since 2011, which aims to provide a common basis for the certification of management system auditors. The scheme developed using ISO 19011 Guidelines for auditing management systems and can be used by personnel certification bodies (e.g. HKICA) operated in accordance with ISO/IEC 17024. In October 2017, IPC received endorsement as a sub-scope of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA), which is the first personnel certification scheme ever to have achieved official endorsement by the IAF. However, IPC does not offer any personnel certification by its own, where IPC offers signatories to recognized personnel certification body members.

HKICA, as the personnel certification bodies that accredited in accordance with ISO/IEC 17024, provides personnel certification to various types of auditors. In June 2018, HKICA has further expanded international involvement and was accepted by IPC as a full member and in October 2018 as one of the IPC MLA Signatory for Management System Auditors and Training on Management System Auditors.

Not only certification auditors, but also a market need on supply of competent internal auditors for the maintenance and implementation of effective management systems for certified organizations.

IPC ISO 17024 Personnel Certification Scheme



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.

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

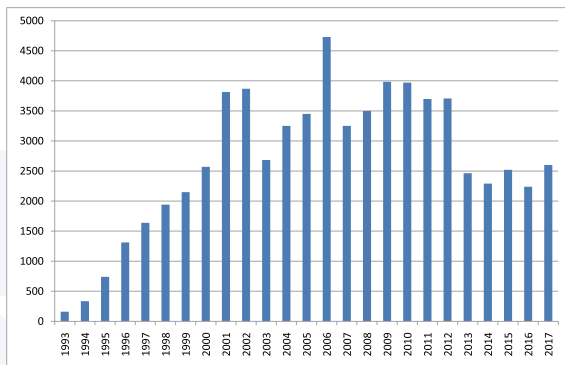


Chapter 4

Continuous Demand in Local Auditing Services

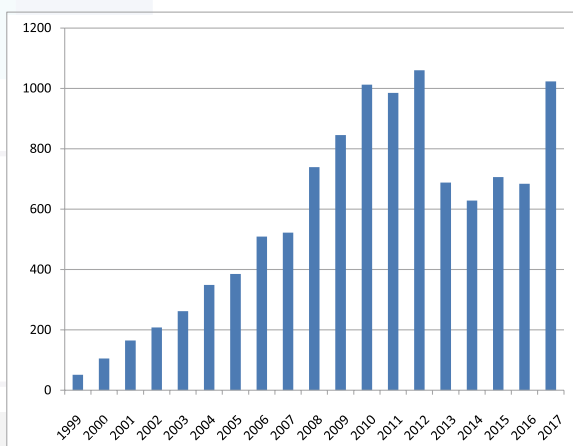


The certification of QMS and EMS will remain to be the major contributors in the certification industry, which will create continuous job opportunities for expertise offering consultancy, management systems maintenance and auditing services within the local and south-east Asia markets, covering both manufacturing and service sectors.



Continuous Demand of ISO 9001 Auditing in Hong Kong

There is an increased in awareness of occupational health and safety (OH&S) has increased these years. According to a research in safety culture conducted by the Hong Kong Occupational Health and Safety Commission (OSHC) in 2010, more than 60% of the working respondents concerned their workplace health and safety risk factors. This gives pressures to employers to implement OH&S management system to identify and reduce of risks in the workplace. The launch of new standard ISO 45001 “Occupational health and safety management systems -- Requirements with guidance for use” in 2018 provided an opportunity to the Hong Kong certification industry to increase the share of market and the demand of auditors and OH&S management system expertise.



Growing Demand of ISO 14001 Auditing in Hong Kong

On the other hand, according to the 2016 statistics of testing and certification activities in Hong Kong conducted by the Census and Statistics Department, there are 670 establishments in Hong Kong, where 196 of which are accredited in accordance with ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories by the Hong Kong Accreditation Service. Routine implementation and maintenance of the management system of a laboratory according to ISO/IEC 17025 requires extensive quality assurance personnel and internal auditors. With the latest update of the ISO/IEC 17025: 2017, the demands in competence of these personnel have been increased in order to deal with the new “goal-setting” approach and other new requirements (such as risk-based thinking).

Due to the recent introduction of ISO 45001: 2018, more certification activities in OH&S management system will be expected in some higher risk sectors, including but not limiting to construction industry and food & beverage services. Renewal of laboratory management systems to conform the latest version of ISO/IEC 17025: 2017 is required to be completed for all accredited laboratories before November 2020, an increase in consultation, training and accreditation activities will be resulted in the period of 2019 to 2020. The demands of auditors and quality assurance expertise of these standards will foreseeable be increased, which create more career opportunities internally.

Chapter 5

Demand in Frontline Quality Professional / Internal Auditor Services



Frontline Quality Professional / Internal Auditor Services Safe Guarding Management System

In Hong Kong, more than 3,000 Small and Medium-sized Enterprises (SMEs) companies obtained certification to various management systems in ISO 9001, ISO 14001, OHSAS 18001 (will be replaced by ISO 45001) management, covering different sectors such as manufacturing industry, construction industry, service providers, software companies, design firms, food industry, shipping companies, retailers, wholesalers, printing companies, etc. Besides, there are more than 300 conformity assessment organizations accredited by the Hong Kong Accreditation Service, including testing and calibration laboratories, inspection bodies and certification bodies.

Effectiveness of audit depends on the expertise, knowledge, skills and eye of the person appointed to conduct the audit. Internal audit can

- identify gaps in performance or processes
- identify non-compliance with legislation and requirements
- getting the management system (MS) ready for audit
- maintaining the standards of performance



Management System without “Professional Man” will not be a Sustainable Management System

Each accredited and certified organizations required at least 3 - 5 audit personnel to deal with daily management system maintenance, internal audit and other quality assurance activities. The demands for effective training and personnel certification are expected to be high. Table 3 summarized the estimated manpower demand forecast for quality assurance personnel.

To maintain an effective and sustainable management system, sufficient and competence quality assurance expertise including internal auditors are essential. **To maintain effective, high quality MS - 97% of the manpower demand for audit services is internal auditor and frontline quality assurance personnel.**

Table 3: Projection of Hong Kong Testing and Certification Manpower Demand

Organizations	Estimated Numbers	Details	Type (estimate no per organization)	Manpower Demand
Accredited Certification Bodies (CB)	25	<ul style="list-style-type: none"> 15 CBs for quality management system (QMS) certification (according to ISO 9001) 15 CBs for environmental management system (EMS) certification (according to ISO 14001) 14 CBs for occupational health & safety management system (OHSMS) certification according to (OHSAS 18001, will be replaced to ISO 45001). 	3 rd party audit personnel (@10)	250
Accredited inspection bodies	21	ISO 17020	3 rd party audit personnel (@10)	210
HKAS accredited organizations	256	229 accredited laboratories (194 accredited to ISO/IEC 17025)	1 st party QA personnel (@ 3)	768
Company certified to ISO 9001	2,239	Various trade and industries	1 st party QA personnel (@ 5)	11,195
Company certified to ISO 14001	684	Various trade and industries	1 st party QA personnel (@ 5)	3,420
Total:				15,843

Chapter 6

Global Opportunity: Development of IATF 16949: Automobile Parts in Asian Market

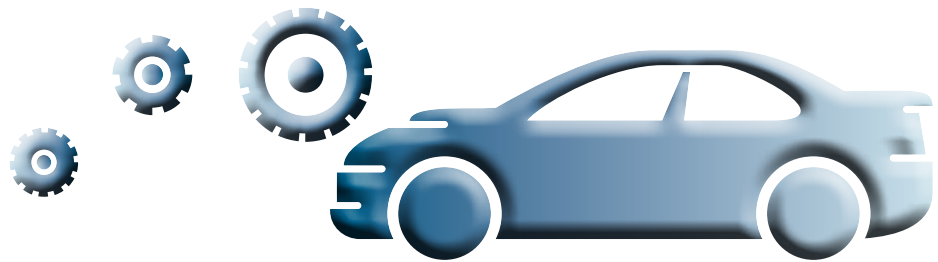


IATF16949 Certification Market

IATF 16949:2016 Automotive Quality Management System Standard is a globally recognized automotive standard and a manufacturing company which is producing parts, assemblies or is providing services to an automotive manufacturer. The technical specification is fully aligned with the structure and requirements of ISO 9001:2015, coupled with the applicable customer specific requirements for automotive production, service and/or accessory parts. The standard aims for continual improvement, emphasizing defect prevention and the reduction of variation and waste in the automotive industry supply chain.

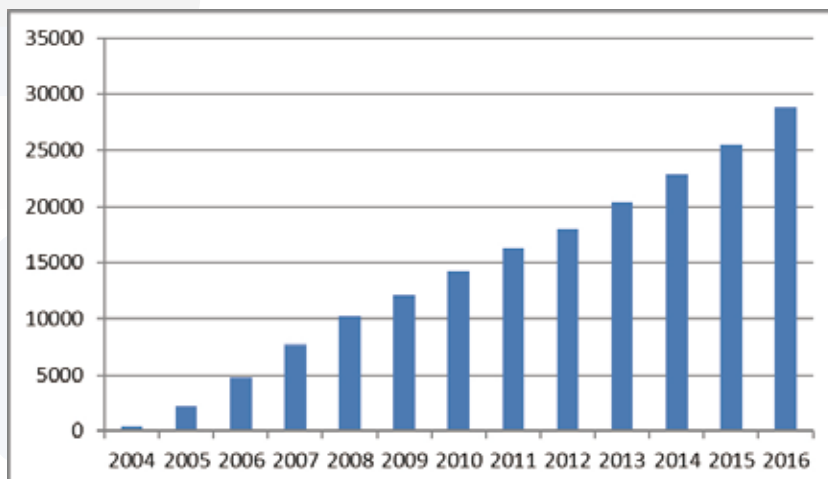
Automotive Company needs IATF 16949 certification

- to survive in the competitive market. All OEM's suppliers must be certified to IATF 16949
- to improve the margins by cutting down on the variation and waste
- for fulfilling customer requirement
- to get new business
- to improve branding and recognition
- to establish a globally recognized management system on quality

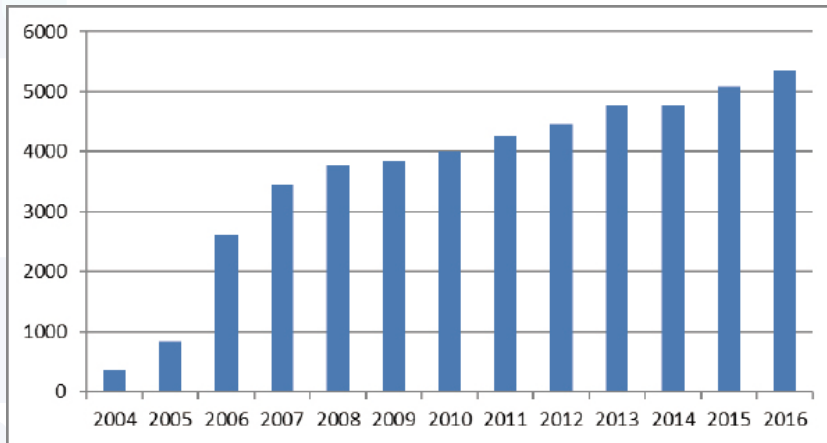


According to the data from the ISO Survey of Management System Standard Certifications in 2017, the total number of ISO/TS 16949 certificates in Mainland China, Taipei and Korea (the biggest market in Asia) were increased dramatically from less than 1,000 in 2004 to 35,572 in 2016. With the latest upgrade of the technical specification to IATF 16949 Standard, International Automotive Task Force (IATF) requires authorized certification bodies (around 42 certification bodies as of October 2018) to conduct IATF 16949: 2016 certification activities. We would foresee a huge demands of competence auditors for certification, second party and internal audits as well as quality assurance personnel to cope with the automotive parts production industry.

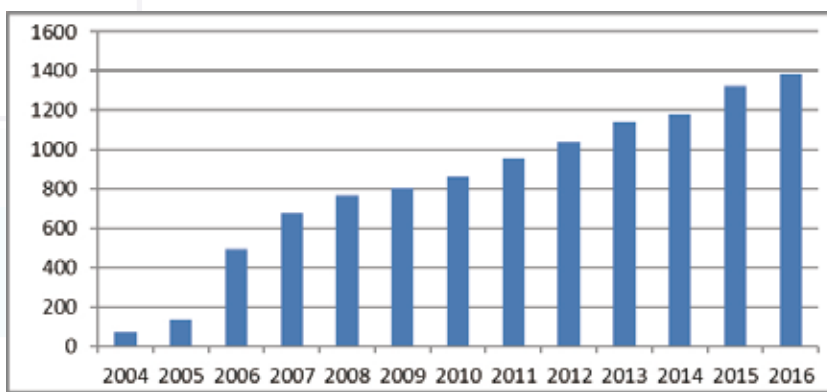
Growing of ISO/TS 16949 certification in Mainland China



Growing of ISO/TS 16949 certification in Korea



Growing of ISO/TS 16949 certification in Taiwan



Demand of Professional Internal audit service

Unlike other standards, IATF 16949 has a sub-clause (7.2.3) that defines requirements for internal auditors. Other than the competency requirement referring to ISO 19011, technical auditors of IATF 16949 should be able to demonstrate competence in:

- Understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of audit
- Understanding of the automotive process approach for auditing, including risk-based thinking
- Understanding of customer-specific requirements
- Understanding of the applicable core tools related to the scope of the audit
- Understanding how to plan, perform, report and close out the audit findings
- Understanding of the manufacturing process being audited, including the process of risk analysis and control plans, the use of appropriate monitoring and measuring equipment to verify product conformity

Internal auditors are obliged to maintain and improve their knowledge and competency by:

- Executing a minimum number of audits per year, as defined by the organization
- Maintaining knowledge on relevant requirements based on internal changes (for example in processes or products technology) and external changes (for example, changes in the standard, core tools, customer requirements, etc.)
- Finally, when the training is provided to achieve competency, documented information should be maintained to demonstrate the trainer's competency

With the leading position of personnel certification status of HKICA, Hong Kong can act as the servicing center providing auditing manpower and training for Mainland, Taipei and Korea markets.

Chapter 7

New Market Potential: ISO 15189 Internal Auditor Services



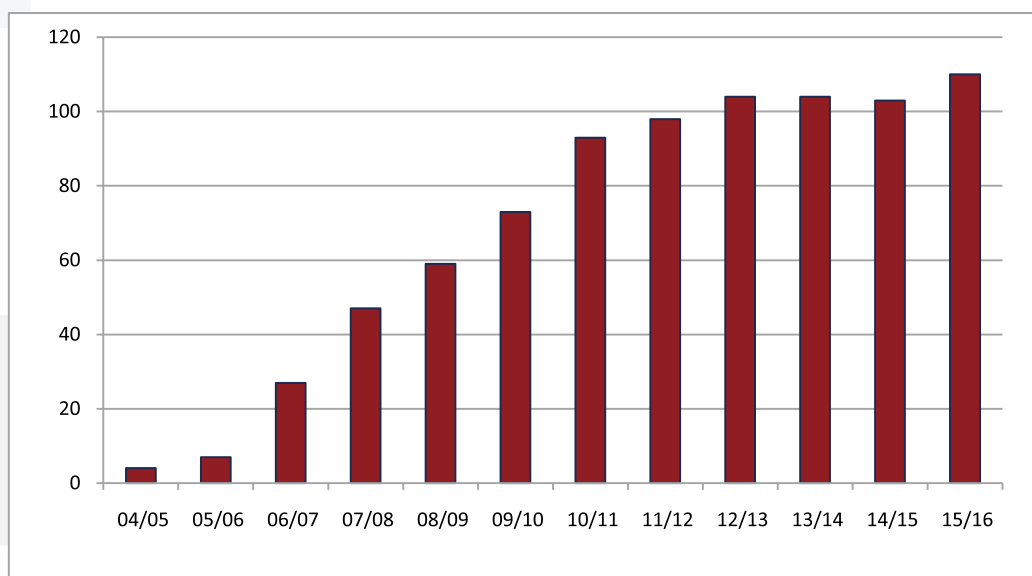
Medical Laboratories in Hong Kong

General public have a high level of expectations to the accuracy and reliability of medical laboratory testing results. Errors in medical laboratory testing results can severely impact the health and even life of patients.

To ensure the accuracy and reliability, medical laboratories have to comply with ISO 15189: 2012 “Medical laboratories – requirements for quality and competence” to demonstrate their quality and competence. ISO 15189 was first published in 2003, it specifies the requirements for quality and competence in medical laboratories. It can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies. Over the years, the number of countries and economies worldwide adopting ISO 15189 has increased from 23 in 2004 to 60 in 2015, such growing provides opportunities not only to testing technologists, but also quality assurance expertise and internal auditors. Besides, the demands in training programmes for implementation and maintenance of laboratory management system in accordance with ISO 15189 will also increase.

- Early before 2004, Hong Kong medical laboratories seek ISO 15189 accreditation from overseas such as National Association of Testing Authorities (NATA) or College of American Pathologists (CAP). The Subsequent accreditation by the Hong Kong Accreditation Service (HKAS) is also based on ISO 15189.
- HKAS provides voluntary accreditation programme for local medical laboratories since 16 February 2004. There are total 106 medical laboratories of which (34 organizations) accredited under the Hong Kong Laboratory Accreditation Scheme (HOKLAS) (Table 6).

Table 6: Number of HOKLAS accredited medical laboratories



Medical Laboratory Audit Professionals

- There is no particular training requirement or prerequisite for internal auditors to perform internal audit. In the past, HKAS arranged courses organized by the National Association of Testing Authorities, Australia for training of accreditation assessors. There is currently no training courses for ISO 15189 provided in Hong Kong for internal auditors and lead assessors.
- Starting from early 1990s, all Hong Kong medical laboratory technologists have to be registered with the Medical Laboratory Technologists Board (MLT Board) under the Regulation of Supplementary Medical Professionals (SMP) Ordinance (CAP 359).

- There are 99 private medical laboratories running in Hong Kong with Medical Laboratory Technologist (MLT) registered in the Medical Technologists Board in accordance with Section 20(3) of the SMP Ordinance for the year 2018. A total of 3,646 Medical laboratory technologists are registered under three parts. Part I registered medical technologists may work independently in a medical laboratory while Parts II and III have to work under supervision (Table 6)
- Board of Directors of a medical laboratory must be a Part I registered MLT.

Table 6: Summary of Registered Medical Laboratory Technologists

Part	No of registrants	Restrictions on practice
I	2,520	
II	1,047	Shall not practice otherwise than under the supervision of a Part I medical laboratory technologist
III	79	Shall not practice otherwise than under the supervision of a Part I medical laboratory technologist
Total	3,646	Last update: August 2018

(<http://www.smp-council.org.hk/mlt/en/intro.php>)

Market Demand on ISO 15189 Internal Auditor Services

HKAS grants accreditation under the Hong Kong Laboratory Accreditation Scheme (HOKLAS) to medical laboratories when relevant accreditation criteria are fulfilled as required by HKAS 002 entitled 'Regulations for HKAS accreditation'. HOKLAS 015 entitled 'Technical criteria for laboratory accreditation (medical laboratories)' which incorporates mandatory requirements of the latest edition of the ISO 15189:2012 entitled 'Medical laboratories – Requirements for quality and competence' and additional HOKLAS policies. According to Clause 5.1.2 (Personnel qualification) of HOKLAS 015 the qualification of each position, including internal auditor appointments, needs to have relevant training and be appropriate to the tasks performed. Thus, the training requirements of internal auditors need to be addressed adequately by the medical laboratory themselves.

Over the year, the ISO 15189 scheme is not well supported by appropriate trained internal auditors though there is demand that the training and qualification of each position including internal auditor appointments, to be appropriate to the tasks performed. Current supply of internal auditors are trained in other inequivalent schemes, such as ISO 9001:2015 entitled 'Quality management systems' and ISO/IEC 17025:2017 entitled 'General requirements for the competence of testing and calibration laboratories'. Similar situation also happened in many countries worldwide. Accordingly, there is an ample need on ISO 15189 trained audit professional services to conduct internal audit of accredited medical laboratories.



Chapter 8

Leading Edge of Hong Kong Auditing Professionals Services



HKICA is the Only Hub That Provides Mutual Recognition link with Mainland and International that Facilitate Auditor Services in South East Asia and Mainland

Benefit of MoU with Mainland Auditing Professionals and IPC recognition

HKICA auditors professional status benchmarked to the International Personnel Certification Association (IPC) and having the mutual recognition with the China Certification and Accreditation Association (CCAA) is an added value and recognition on competency of our professional service; the greatness opportunity and key stepping stone for Hong Kong testing and certification industry going global.

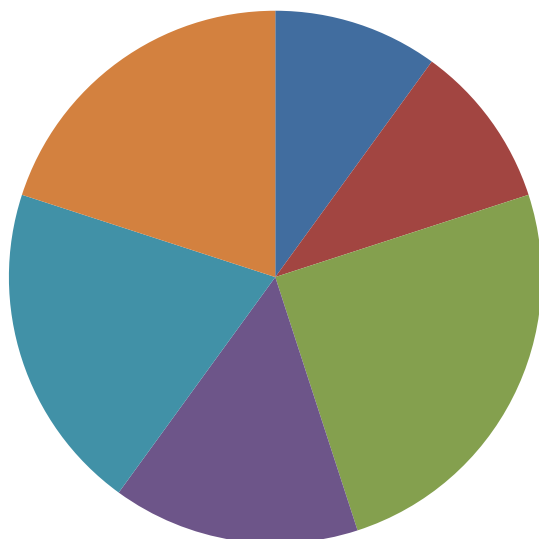


With the feedbacks received from the visits to Taipei, Singapore and Beijing by members of HKICA, together with the survey feedback received from visitor of exhibition, Hong Kong are well positioned in providing auditing services in south-east Asia.

Leading Edge of Hong Kong Auditing Services

- Recognition of the competence. Certification of QMS auditors by HKICA is accredited in accordance with ISO/IEC 17024 "General requirements for bodies operating certification of persons", where HKICA has strong association with various national and international personnel certification bodies including CCAA and IPC and facilitate the recognition of HKICA's certification status
- Proximity of Hong Kong to the Mainland, Taiwan and other parts of south-east Asia. South-east Asia is one of the major manufacturing centers worldwide. Hong Kong certified auditors can provide fast response and support to the audit services for manufacturers in the south-east Asia region
- HKICA as center of Asia provides ISO 17024 international registration service of personnel
- Have similar cultural background within Asian countries and Mainland
- Bilingual good command in English and Chinese avoiding possible misunderstanding
- Competent and are conversant with the standards used for auditing





- Good language and communication skills
- Leadership with international lifestyle
- High work efficiency and professional experiences
- High education level and Professional knowledge
- Responsibility and integrity
- Trustworthiness with professional ethics

Hong Kong Auditor can become professional in Mainland

国家职业资格目录清单

专业技术人员职业资格（共计58项）

序号	职业资格名称	实施部门 (单位)	设定依据
1	教师资格	教育部	《中华人民共和国教师法》 《教师资格条例》（国务院令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598号）
10	监理工程师	住房和城乡建设部、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	住房和城乡建设部、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	住房和城乡建设部、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	住房和城乡建设部、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〕58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）
51	认证人员职业资格	质检总局	《中华人民共和国认证认可条例》（国务院令390号）
52	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343号） 《音像制品管理条例》（国务院令341号） 《出版专业技术人员职业资格条例》（职改字〔1986〕第41号） 《出版专业技术人员职业资格暂行规定》（人发〔2001〕86号）
53	统计专业技术资格	国家统计局、人力资源社会保障部	《统计专业职务试行条例》（职改字〔1986〕第57号） 《统计专业技术资格考试暂行规定》（人职发〔1993〕1号） 《关于印发高级统计师资格评价办法（试行）的通知》（人社部发〔2011〕90号）



Background of Information HKICA



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

Hong Kong Institution of Certified Auditors (HKICA), a professional body for management auditors, was established in 2006. Its Executive Board comprises members from universities, public authorities, governmental organizations, certification bodies, management system consultants in Hong Kong. HKICA provides personnel certification services to the quality, environmental, occupational health & safety, food safety, laboratory and other management systems auditing professionals in Hong Kong; to meet the ever changing need of these industries and the expectation of the community; and a bridging function of certification services for all industrial trades of local, Asian and international enterprises.

HKICA provides fair and impartial certification service to ISO 17024 international standard for Quality Management System ISO 9001 auditors in affirmation of their competency in professional skills and knowledge. Our certified auditor system bench marking to ISO 17024 international standard has been accredited by China National Accreditation Service for Conformity Assessment (CNAS) in May 2016.

HKICA has further expanded its international involvement and was accepted as IPC full member in June 2018 and in October 2018 as one of the IPC MLA Signatory for Management System Auditors and Training on Management System Auditors.

Missions of the HKICA include the following objectives:

- Promote the status of management system auditors to the public as a profession;
- Establish a local based lead auditors and auditors registration system in accordance with ISO/IEC 19011 & relevant standards and to maintain a database of all registered auditors in the HKICA website for the benefit of the industry;
- Set up personnel certification schemes for inspectors in accordance with the principle of ISO/IEC 17020;
- Deliver auditing related seminars and workshops which are of common interests to local and overseas auditing profession;
- Provide a focal point where registered auditors, certified managers and registered inspectors can get together for exchange of experience & knowledge and fostering of future developments in the related professions;
- Liaise with overseas equivalent bodies for reciprocal recognition of auditors registration schemes; and
- Approve auditing and related training courses for recognition by the auditing profession and the public in accordance with the international practice.

