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

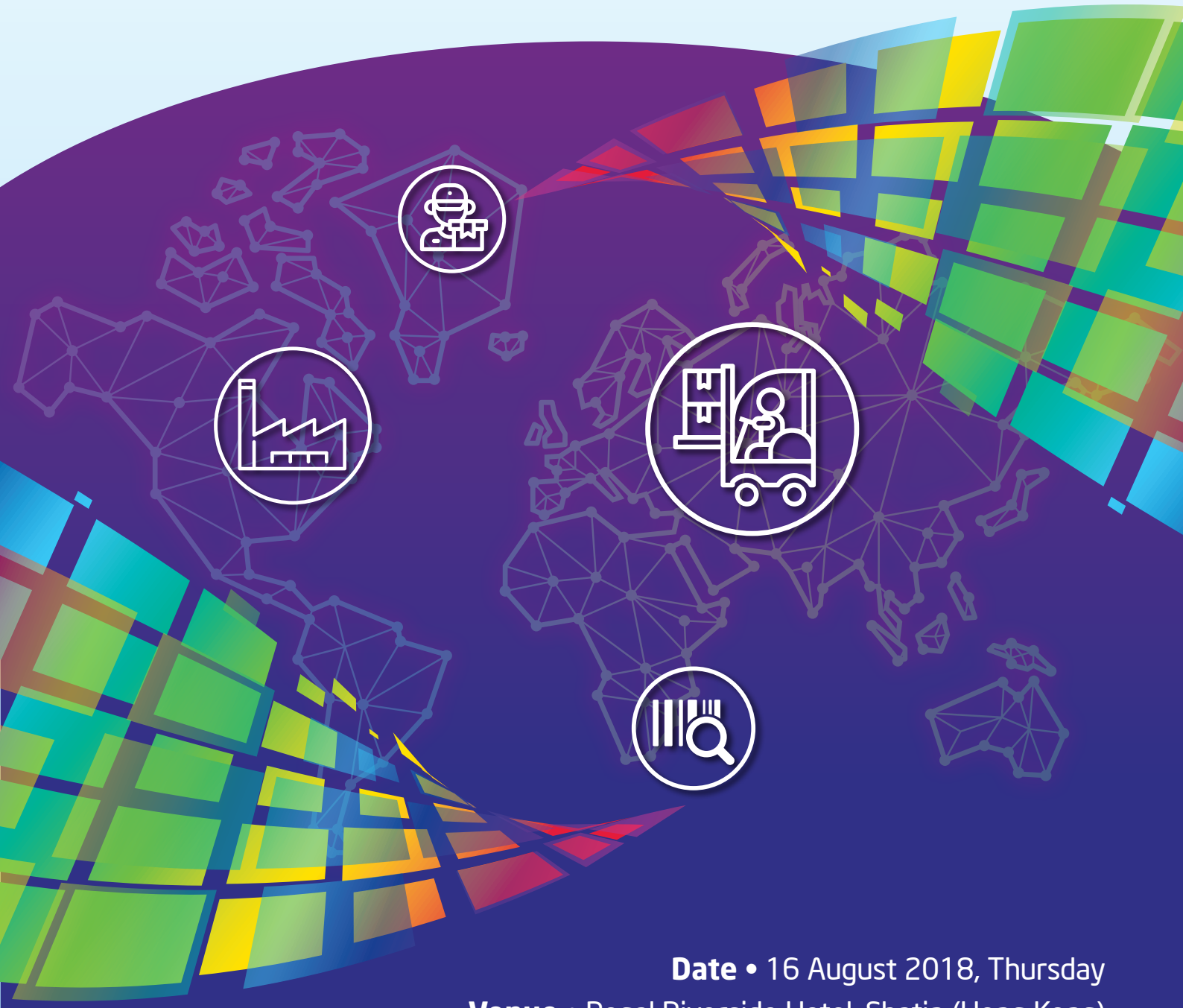
CCAA

HKIE 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

Import/Export, Plant, Control and Risk Management



Date • 16 August 2018, Thursday

Venue • Regal Riverside Hotel, Shatin (Hong Kong)

Time • 8:45 a.m. (registration) – 5:00 p.m.

ISO 9001:2015 Challenges and Opportunities for Auditors

Import/Export, Plant, Control and Risk Management

Programme Rundown

Time	Topic	Speaker
08:45 -0 9:15	**Registration**	
09:15 - 09:30	**Welcoming Speech**	**Ir Dr Tommy Lo** President of Hong Kong Institution of Certified Auditors
09:30 - 09:35	**Photo taking and Souvenir presentation with speakers**	
09:35 - 10:10	**Competence vs Qualification Personnel Certification Programs**	**Osman Vural** Chairman The International Personnel Certification Association
10:10 - 10:45	**ACO Smart design of grease separator and kitchen hygienic drainage solution**	**Jiri Musil** Area Manager, ACO Industries
10:45 - 11:05	**Tea Break**	
11:05 - 11:40	**中國人員認證制度的最新發展**	**孫兵** 認證人員能力評價中心發展研究部 中國認證認可協會 (China Certification and Accreditation Association)
11:40 - 12: 15	**The Impact of ISO 9001 to the change of laboratory management and how this improves international trade**	**Dr Eric Sze** Assistant Professor Open University of Hong Kong
12:15 - 12:30	**Discussion and Q & A**	
12:30 - 14:15	**Lunch**	
14:15 - 14:20	**Photo taking and Souvenir presentation with speakers**	
14:20 - 14:55	**Risk management of Ngong Ping 360**	**Edward Chow** Head of Safety and Quality Ngong Ping 360
14:55 - 15:30	**The Backgrounds of ISO9001, Comparison of ISO9001:2008 & ISO9001:2015; and Supply Chain (Export + Import)**	**Frank Sheun** QA Manager, Paul Y., Engineering Group
15:30 - 15:50	**Tea Break**	
15:50 - 16:25	**Practice and Experience of Auditors – corporate management risk for Export/ Import, Plant and Control**	**Ir Dr Tommy Lo** President of Hong Kong Institution of Certified Auditors (Hong Kong)
16:25 - 17:00	**Discussion and Q & A**	

Osman Vural
Chairman, The International Personnel Certification Association

Competence vs Qualification Personnel Certification Programs

Personnel certification has been and will continue to remain a desirable asset for any modern professional. Achieving certification often represents a significant investment in time, effort and expense. Frequently, candidates have to choose between a “competence-based” or a “qualification-based” type of certification program. In most cases, qualification-based personnel certification is easier and less expensive to achieve. But is it actually worth it? What is the difference between a competence-based versus a qualification-based personnel certification program?

In ISO Standard 19011:2011, Guidelines for auditing management systems, competence is defined as “the ability to apply knowledge and skills to achieve intended results.” Competence-based certification means that the Personnel Certification Body (PCB) is expected to examine a candidate’s knowledge, skills, personal attributes and qualifications specific to the program and/or scope of certification. On the other hand, qualification-based certification relies on an applicant's education and qualifications, rather than on the basis of measurable competence. The following short dialog is catalytic to understand, in a few words, the difference between “competence” and “qualification.”

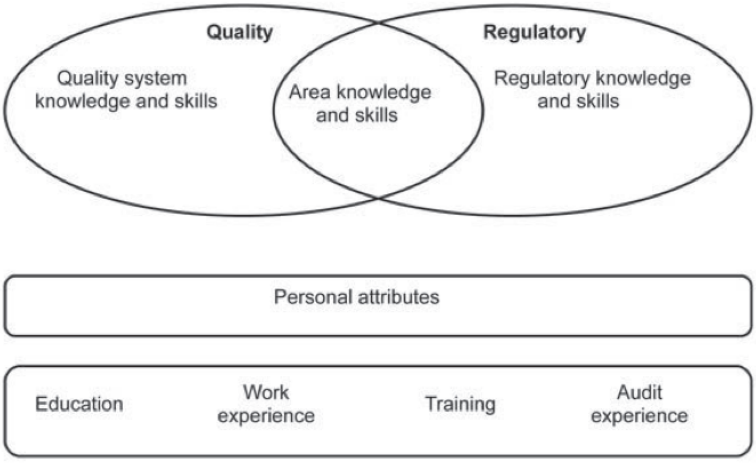
- “Do you know how to drive a car?”
- “I was trained and acquired a driving license but I am still not confident to drive a car.”
- “That means you have the qualifications but not the competence.”

There are college drop-outs who are CEOs of Fortune 500 companies because they have competencies, not qualifications. Therefore, having both qualifications and competencies helps immensely but people can still excel through competencies rather than qualifications.
Recognizing this fact, the International Organization for Standardization (ISO), through ISO/IEC Standard 17024 Conformity Assessment – General requirements for bodies operating certification of persons, mandates that the certification of persons should be based on the demonstration of competencies and not the demonstration of qualifications. ISO/IEC 17024 sets the requirements and the framework, at a global level, for the operation of Personnel Certification Bodies. By using ISO/IEC 17024, business, industry and other key stakeholders have recognized that competency-based certification is the optimum way of achieving confidence in persons certified by PCBs. ISO/IEC 17024 does allow some variation in how competence is demonstrated; consequently different PCBs may interpret and apply the means for competency assessment in different but technically valid ways.

Still, there are PCBs that insist in offering, non-accredited, qualification-based programs on the assumption that qualification equals competence. While that assumption may be correct in some cases and may continue to be acceptable to a range of users, it is less acceptable for those who operate in contexts that require a more rigorous demonstration of competence based on a valid examination. This creates considerable confusion to the market and to certification candidates. And, of course, as qualification programs don’t satisfy all competence requirements they are non-accreditable.
Another key difference among the competence and qualification-based programs is the

change of emphasis from training to examination. Qualification based programs emphasize training while competence based programs emphasize the results of training by assessing competence through one or more methods of examination which must be valid, reliable and independent. Competency-based certification programs define first the competencies required so that they can be properly examined.

So, is it possible to distinguish a competency-based from a qualification-based program? The answer is simple: Check for the accreditation of the PCB that provides the certification program to see if it is based on ISO/IEC Standard 17024 requirements. Then, check to see if the PCB's scope of accreditation includes that program. Finally, check to see if the PCB's accreditation is provided by an Accreditation Body that is a Multilateral Recognition Arrangement (MRA) signatory member of the International Accreditation Forum (www.iaf.nu) or that the PCB is a signatory under the MLA of the International Personnel Certification Association (www.ipcaweb.org).



Example of Competence for Quality Management System Auditors (ISO 19011)

IPC is the scheme owner of the world-wide operated "IPC Management System Auditors certification scheme". At the beginning of 2015 IPC had applied to IAF to evaluate IPC's auditor certification scheme. Since then our scheme has been evaluated in depth by IAF experts/committees. As a result, IPC has received the IAF endorsement as a sub-scope of the IAF MLA, during the 31st IAF General Assembly that took place on 28 and 30 October 2017 at Vancouver , Canada . The IPC Management Systems Auditor Certification Scheme is also the first personnel certification program to be endorsed by IAF. Up to now, tenths of thousands of MS auditor certificates have been issued by members of the IPC MLA . It means that the IPC scheme has been globally adopted as the common competency based personnel certification scheme for Management System Auditors.

IPC sets, since the 90's, voluntary standards for the certification of Management Systems (MS) auditors and provides the standard and the framework for independent, recognized 3rd party certification of Management System Auditors based on ISO/IEC 17024. The two certification grades that IPC recognizes are IPC MS Auditor, and IPC MS Lead Auditor. Until the day of IAF endorsement IPC schemes were used solely by the IPC MLA signatories. The "IPC Management System Auditors" may be used now by all PCBs that are accredited by IAF MLA signatories and are becoming IPC members.

HKICA

Workshop on ISO 9001:2015 Challenges and Opportunities for Auditors - Import/Export, Plant, Control and Risk Management
Regal Riverside Hotel, Shatin (Hong Kong)
16 August 2018, Thursday

Competence vs Qualification
Personnel Certification Programs

IPC
International Personnel Certification Association

Osman Vural
IPC Chairman

www.ipcaweb.org

Competence vs Qualification

IPC

the message

- As a profession, we auditors are not doing enough. We are failing our colleagues in top management and if we are failing business then we are failing the economy.

www.ipcaweb.org

Competence vs Qualification

IPC

www.ipcaweb.org

Competence vs Qualification

IPC

CB Side	*Client Side*
Auditor Competencies	**Effective Audit + Added Value**

www.ipcaweb.org

Competence vs Qualification

IPC

QUALIFICATION?

COMPETENCY ?

www.ipcaweb.org

Competence vs Qualification

IPC

www.ipcaweb.org

Competence vs Qualification

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Competence vs Qualification

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Competence vs Qualification

the most common mistake

- The most common mistake in auditing world is that; qualification we achieved is enough.

what we have to say today

- Qualification is not enough to perform effective audits. Three components are required to carry out effective and generating add value auditing. ***Education, Skills and Experience***. Combination of these three elements is called as **Competency**.

www.ipcaweb.org

Competence vs Qualification

www.ipcaweb.org

Competence vs Qualification

Do you want?

Why you don't want?

www.ipcaweb.org

Competence vs Qualification

INTERNATIONAL STANDARD **ISO/IEC 17024**

Conformity assessment — General requirements for bodies operating certification of persons

www.ipcaweb.org

Competence vs Qualification

diploma training vs validated examination

www.ipcaweb.org

Competence vs Qualification

IPC-PL-11-006 IPC Certification Scheme
"IPC Management System Auditors",
Issue Date 28/10/2017,

www.ipcaweb.org

Competence vs Qualification

What is IPC?

IATCA 1995

IPC 2006
International Personnel Certification Association

www.ipcaweb.org

Competence vs Qualification

IPC International Personnel Certification Association

INTERNATIONAL ACCREDITATION FORUM IAF

"IPC Management System Auditors certification scheme"
received endorsement as a sub-scope of the IAF MLA,
during the thirty-first IAF General Assembly
that took place on 28 and 30 October 2017 at Vancouver, Canada

detailed information
https://www.iaf.nu/articles/Scopes/16

www.ipcaweb.org

Competence vs Qualification

HKICA

Hong Kong Institution of Certified Auditors
Full member of IPC, Since June 2018

www.ipcaweb.org

Competence vs Qualification

IPC International Personnel Certification Association

Thank You

www.ipcaweb.org

Jiri Musil
Area Manager, ACO Industries

ACO Smart design of grease separator and kitchen hygienic drainage solution

ACO Drainage Management in Commercial Kitchen

ACO Partnerships

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

ACO is a CEN consultant member since more then 15 years

Certificates

Quality System Certification

ISO 9001:2008 (SINCE 1995)

IMO Marine Equipment Directive certificate modul D (SINCE 2004)

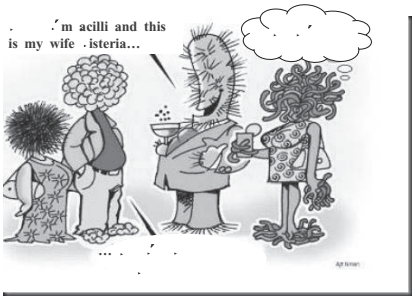
Product Certification

DNV·GL
BUREAU VERITAS
Lloyd's Register
ABS TYPE APPROVED PRODUCT
kiwa
TÜVRheinland LGA Genau. Richtig.
DANISH TECHNOLOGICAL INSTITUTE

Current Kitchen Drain System

Problems Analysis

Welcome to the party!



Solution to Traditional drainage

Rentokil The experts in Pest Control

ECOLAB Diversey for a cleaner, healthier future

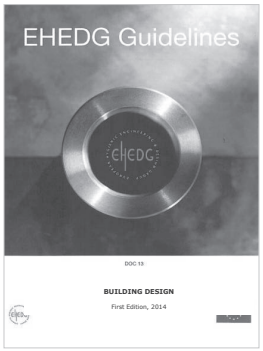
All Chemical Companies!

The Answer: Hygienic Drainage!

Hygienic design is essential to minimize bacteria traps.

Hygienic design is every part can be cleanable

ACO - member of EHEDG working group for Building design guidelines - issue 2014



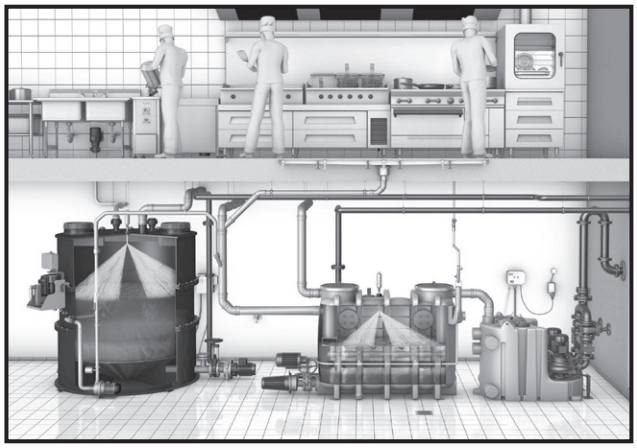
EHEDG: European Hygienic Engineering Design Group

We call it - HygieneFirst.

Because it covers all main requirements from drainage systems at the same time.

HygieneFirst

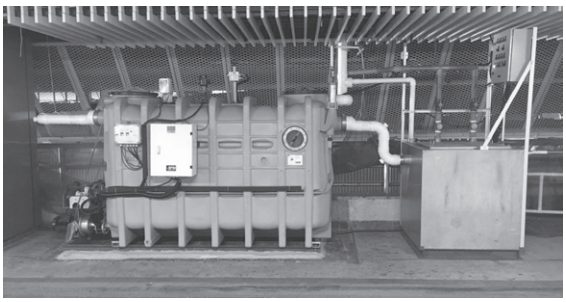
1	Food Safety	To protect people and brand
2	Costs	To stay competitive
3	Health & Safety	To secure the work environment



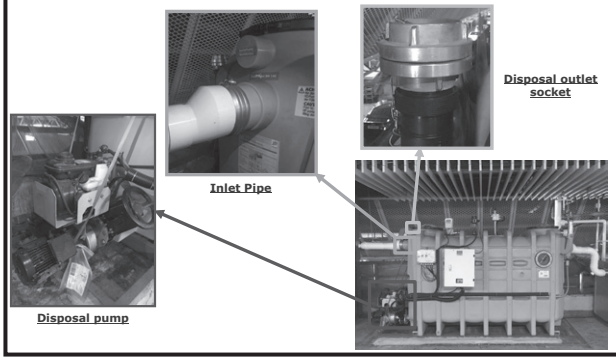
Full Disposal Separator - HydroJet

Job Reference – Maxim's group restaurant at Shun Tak Centre

Job Reference – Maxim's group restaurant at Shun Tak Centre



Job Reference – Maxim's group restaurant at Shun Tak Centre



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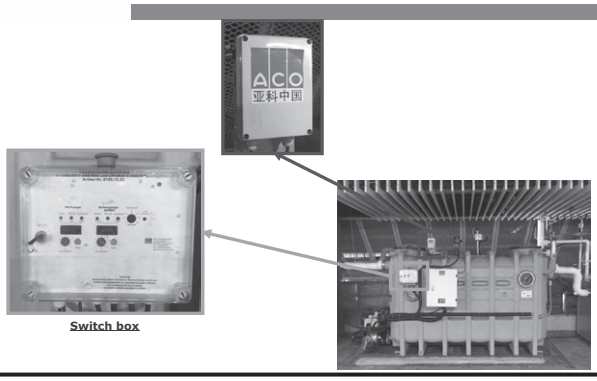

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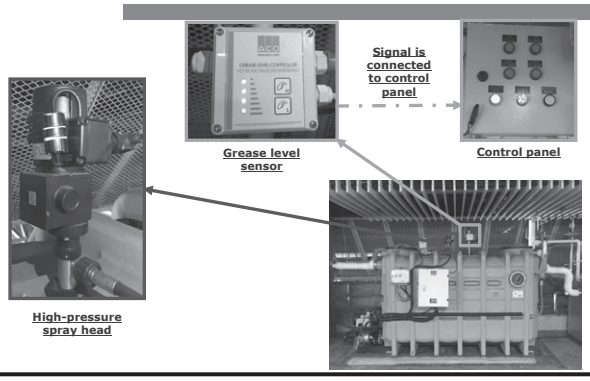

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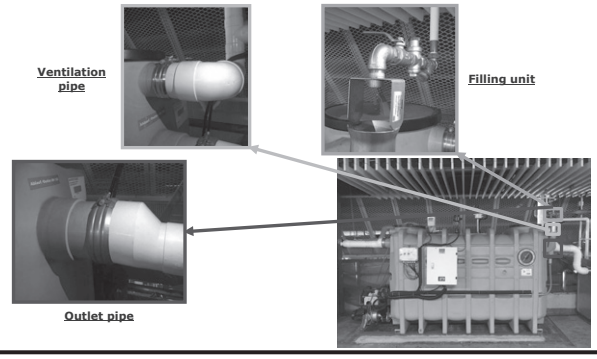
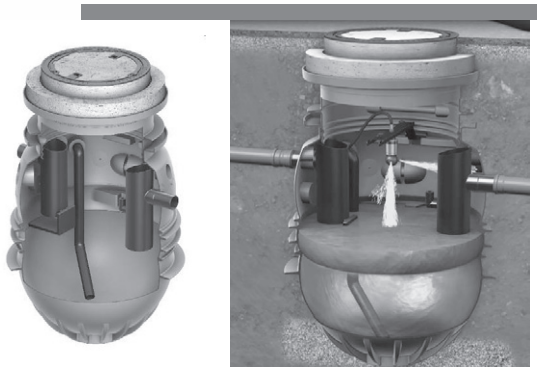


Underground Separator - Lipumax



Underground Separator - Lipumax

Application

Those area without underground equipment room/not available to install free standing equipment.

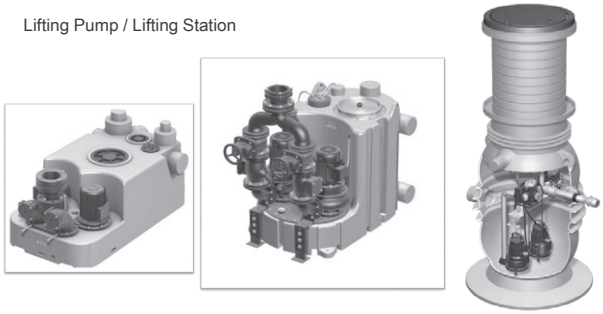
Features

- Rotate Molding Technology
- Compare to Concrete & Glass fiber plastic material, much more stable and high compression strength
- Anti Floating Design
- With different loading class covering
- 100% sealed, 100% no leakage
- Guarantee for 35 years using
- One month discharge once
- Other accessary are available:
  - ✓ Cleaning system
  - ✓ Remote control
  - ✓ Leveling alarming

Waste water treatment flow:

NS2 (2L/s ≈ 7.2m³/h)
NS4 (4L/s ≈ 14.4m³/h)
NS5.5 (5.5L/s ≈ 19.8m³/h)
NS7 (7L/s ≈ 25.2m³/h)
NS8.5 (8.5L/s ≈ 30.6m³/h)
NS10 (10L/s ≈ 36m³/h)

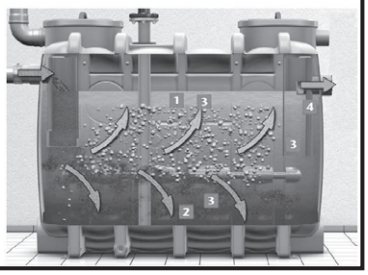
Lifting Pump / Lifting Station



Grease Separator Dimentioning & Difficulties Factor

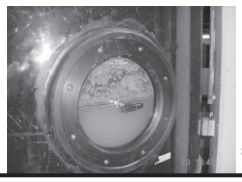
The consistency of kitchen wastewater

1. Separable constituents
2. Solids
3. Suspended constituents
4. Emulsified constituents



Emulsion

Non separated



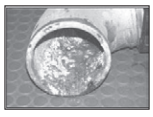
Separated

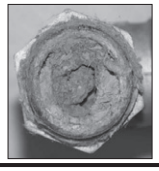
Do we necessary to use grease separator?

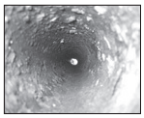
The piping of the **building** can get **clogged** due to heavy sedimentation with grease.

Effects:

- **The operation in the kitchen (or the slaughterhouse) must be stopped.**
- **Significant funds and time have to be invested to clean the pipes or (in the worst case) to replace defective piping systems.**







Dimensioning

Grease separators according to EN 1825

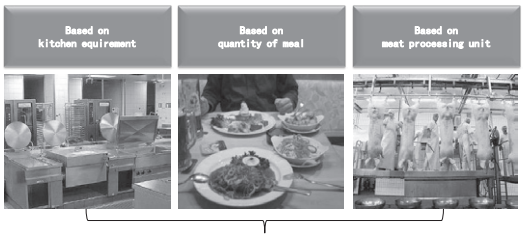
EN 1825 – Part 1

Manufacturing principles and testing of grease separators

EN 1825 – Part 2

Dimensioning and installation of grease separators

Dimensioning (EN 1825) European Standard



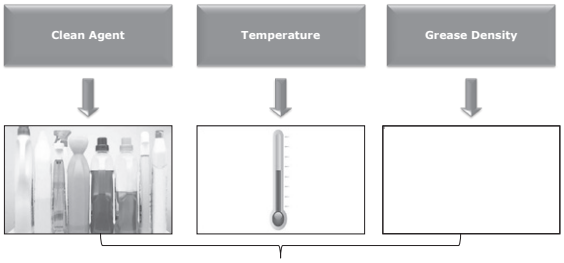
Basic water flow (l/s)

Difficulties ratio

Normal Size (L/s)

Difficulties Factor

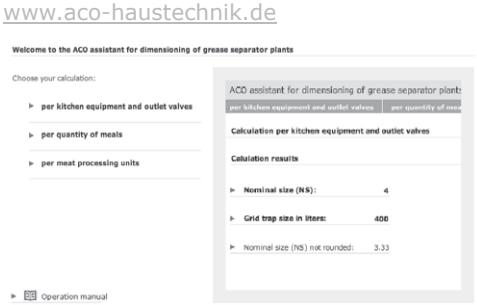
According to EN1825，Difficulties factor is coming from:



All these factors reduce the separation effect

Calculate from the ACO WEB

www.aco-haustechnik.de



ACO – McDonald's France

Name: McDonald's Restaurant

Country: France

Products: ACO channels, gullies and shoe scrapers, access covers

ACO and McDonald's Activities

ACO Drainage Solutions - McDonald's

Country	Projects	Product	Additional
France	Multiple projects	SS Tray Channel / Vertical outlet 200x1000 mm	Mesh Grating
Commun. Directly w / McD		SS Tray Channel / Horizontal outlet 200x1000 mm	Mesh Grating
		SS Floor Gully / Vertical outlet 300x1000 mm	Mesh Grating
		SS Floor Gully / Horizontal outlet 300x1000 mm	Mesh Grating
		SS Floor Gully / Vertical outlet 400x400 mm	Mesh Grating
		SS Floor Gully / Horizontal outlet 400x400 mm	Mesh Grating
		SS Sanitary Gully 150x150 mm	Wave Cover
		SS Access Cover 400x400 mm	
		SS Slot Channel 20x1000 mm	
		SS Shoe Scraper 1500x500 mm	
Serbia	1 project	SS Floor Gully / Vertical Telescopic 250x250 mm	Mesh Grating
		SS Floor Gully / Vertical Telescopic 200x200 mm	Mesh Grating
Croatia	9 projects	External Line Drainage	Multiline
		External Line Drainage	Monoblock
		SS Sanitary Gully 150x150 mm	
		Grease Separator / Lipumax SF200	
		grease Separator / Lipumax SF700	
		Roof Gully / Spin roof	
		SS Floor Gully / Horizontal outlet 200x200 mm	Mesh Grating
Finland	Multiple projects	SS Tray Channel / Vertical outlet	
Commun. Directly w / McD		SS Floor Gully / Vertical outlet	
Germany	Multiple projects	Grease Separator / Lipumax SF700	
Ukraine	Multiple projects	Grease Separator / Lipumax SF100	
Poland	Multiple projects	Grease Separator / Lipumax SF700	
Austria	Multiple projects	Grease Separator / SS Floor Gully	
Portugal	Multiple projects	SS Floor Gully	Mesh Grating
Commun. Directly w / McD		SS Box Channels	
Spain	Multiple projects	Hygienic box channels / Hygienic gullies	Mesh Grating
Commun. Directly w / McD			

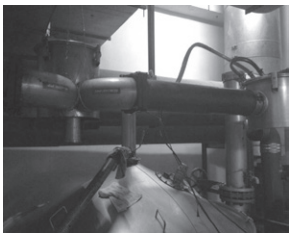
References

References

BMW Shengyang

References

10 years application in Shanghai

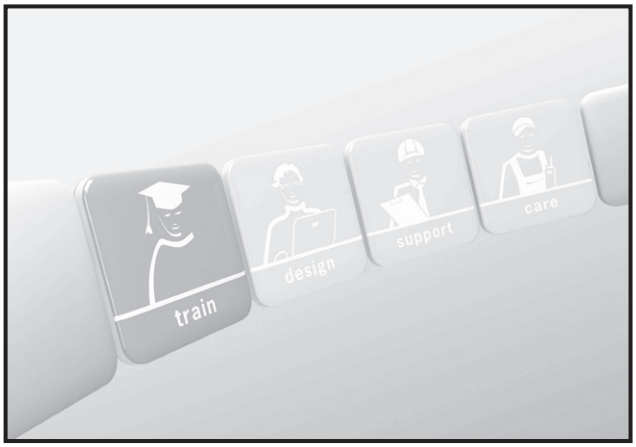


Hong Yi Square

How could we support your business?

ACO is not only channels and gullies...

ACO is the only **global supplier** of a complete **drainage solution** for Waste Water Management systems.



Team of experts for global support

ACO dedicated support by global expert team – **We go where You go**

- **ACO design supported** by competence center experts
- **ACO global food expert team –** experts in all countries to ensure local professional support
- **ACO knowledge management system** – to ensure highest level of professional knowledge of ACO expert team around the globe

ACO connecting industry experts

Waste Water Management is a **complex task** to be addressed by all **industry experts**

ACO connects industry experts

ACO focus on drainage integration within the whole preparation environment

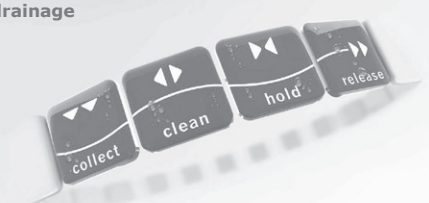
- **ACO complex solution** offer for any project
- Close cooperation with **global specialists** as well as **process technology** suppliers for appropriate drainage layout design
- Tight cooperation with major **flooring specialists** to offer **safe and durable solution for drainage connection to floor**
- Development of **cleaning processes** with major suppliers of cleaning technology

FCSI · Electrolux · Sika · BASF · Diversey · ECOLAB

These Companies Trust Our Grease Separator Solutions

SELGROS CASH & CARRY · Auchan · DANONE · Kaufland · McDonald's · Heineken · IKEA · Coca-Cola · BURGER KING · Mondelēz International · GROUPE LACTALIS · globus · METRO GROUP · . . .

ACO. The future of drainage



Dr Eric Sze
Assistant Professor, Open University of Hong Kong

The Impact of ISO 9001 to the change of laboratory management and how this improves international trade

THE IMPACT OF ISO 9001 TO THE CHANGE OF LABORATORY MANAGEMENT SYSTEM AND HOW THIS IMPROVES INTERNATIONAL TRADE

Presented by Dr. Eric T. P. Sze
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GO FURTHER 高飛 創未來

Dr. Eric Sze

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- Adjunct Assistant Professor, Department of Chemistry, The Chinese University of Hong Kong
- Fellow member and Strategic Development Committee Chairman, HKICA
- HKICA Certified Lead Auditor
- CCAA Registered Auditor
- Ex-Senior Accreditation Officer, Hong Kong Accreditation Service (HKAS)

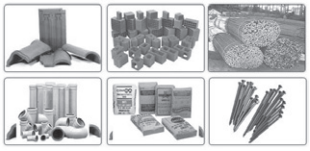
LABORATORY TESTING IN FACILITATING TRADE

Trading of Products

Foods

Consumer Products

Construction Materials



Chinese medicines
Jewelry
and many more……

Duplicate Testing and Technical Trade Barriers

- Manufacturers and buyers using testing services to evaluate the compliance and performance of their products
- Testing results may vary if laboratories perform differently
- Duplicate testing may be resulted by manufacturers, buyers and regulators……Increases in cost and creates technical barriers of trade (TBT)
- Standardization are thus required to minimize the difference in practices

Standardization of Testing Practices to Facilitate Trade

- The ISO Committee on Conformity Assessment (CASCO) developed an ISO 9001 based Standard for laboratories to demonstrate that they operate competently and generate valid results
- It is also used as criteria for accreditation of laboratories
- Through the use of accreditation and implementation of Laboratory Management System, wider acceptance of results between countries can be achieved
- Test reports from laboratories following this Standard i.e. (ISO/IEC 17025) can be accepted from one country to another without the need for further testing
- Decrease in costing and improves international trade

Benefits of Laboratory Management System Accreditation

- Recognition of competence by third party authoritative body
- Marketing and business advantages
  - promote their business (e.g. 'endorsed' testing reports)
- Minimization of retesting and reworking of goods
  - Testing can be expensive and time consuming
  - Important to test correctly the first time (rework costs may be high)
  - Avoid inconsistence results between the buyer and the manufacturer
- Governments using accreditation services in their policy making
  - Important of citizens' health and safety, and the environment
  - use accredited services to reduce their workloads in market surveillance and control of importing and domestic goods

HISTORY OF LABORATORY MANAGEMENT SYSTEM

Development of ISO Guide 25

- The first International Laboratory Accreditation Conference in Copenhagen (1977) triggered the development of the 1st international guidance document for laboratory accreditation
- Named as ISO Guide 25: 1978 "General requirements for the competence of calibration and testing laboratories"
- Developed by the International Standard Organization (ISO) Committee on Conformity Assessment (CASCO)
- Revised in 1982 and 1990
- Superseded by ISO/IEC 17025 in 1999

Upgrade to International Standard

- ISO/IEC 17025:1999 have been divided in two main sections:
  - Clause 4. Management System Requirements
  - Clause 5. Technical Requirements
- Introduced new technical requirements
  - Validation of new methods
  - Sampling
  - Professional judgment/interpretation by the laboratory
  - Measurement uncertainty (MU)
- Traceability was subdivided into requirements for calibration and testing laboratories
- The management system has referenced to ISO 9001:1994 and ISO 9002:1994

2nd Edition: ISO/IEC 17025: 2005

- Aligned the Management System with ISO 9001: 2000
- A new and separate clause on "improvement"
- Minor changes to the terminologies used
  - Clause 4.2 Management System (used to be Quality System)
  - Clause 4.7 Service to the Customer (used to be Service to the Client)
  - Changed "clients" to "customers"
  - Changed "quality system" to "management system" (defined as "quality, administrative and technical systems that govern the operations of the laboratory")

ISO/IEC 17025: 2005 vs ISO 9001

- Clause 4 requirements for management incorporates with requirements of ISO 9001 that are relevant to testing and calibration
- Laboratories comply with ISO/IEC 17025 generally in accordance with the principles of ISO 9001

https://www.nist.gov/sites/default/files/documents/2017/07/05/joint-iso-iec-17025-communique-2017-final-signed_1.pdf

PUBLISH OF LATEST LABORATORY MANAGEMENT SYSTEM

Latest Edition ISO/IEC 17025:2017

- Published on 30th November 2017
- International Laboratory Accreditation Cooperation (ILAC) endorsed a 3-year transition period for the implementation of this version (General Assembly 2016 Resolution GA 20.15)
- apart from "competence" mentioned in previous versions, this version also highlighted "impartiality and consistent operation" of laboratories
- Aligned with ISO 9001:2015, including risks and opportunities
  - Still separate "Documents" and "Records", instead of "Documented information" in ISO 9001: 2015
  - Add an option to maintain the management system in accordance with ISO 9001
- New definition of "laboratory" has been added

New definition of laboratory

Body that performs one or more of the following activities:

- testing
- calibration
- sampling, associated with subsequent testing or calibration

The above activities are regarded as "Laboratory Activities"

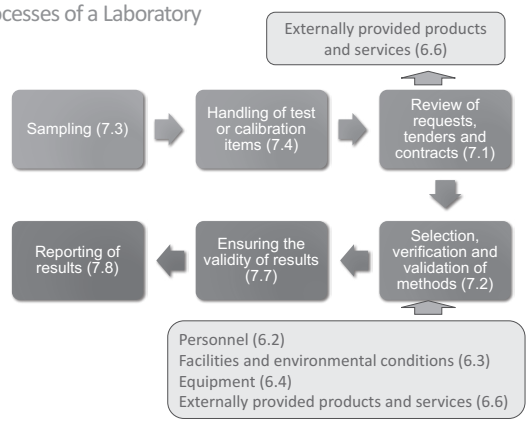
New Structure

- Align with the layout of ISO 9001 and other existing ISO/IEC conformity assessment standards

ISO/IEC 17025: 2017

4. General Requirements	7. Process Requirements	7.11 Control of data and information management
4.1 Impartiality	7.1 Review of requests, tenders and contracts	8. Management System Requirements
4.2 Confidentiality	7.2 Selection, verification and validation of methods	8.1 Options
5. Structural Requirements	7.3 Sampling	8.2 Management System documentation
6. Resource Requirements	7.4 Handling of test and calibration items	8.3 Control of documents
6.1 General	7.5 Technical records	8.4 Control of records
6.2 Personnel	7.6 Evaluation of measurement uncertainty	8.5 Actions to address risks and opportunities
6.3 Facilities and environmental conditions	7.7 Ensuring the validity of results	8.6 Improvement
6.4 Equipment	7.8 Reporting of results	8.7 Corrective Actions
6.5 Metrological traceability	7.9 Complaints	8.8 Internal Audits
6.6 Externally provided products and services	7.10 Non conforming work	8.9 Management Review

Processes of a Laboratory



Use of Information Technologies

- Incorporates the use of use of computer systems, electronic records and the production of electronic results and reports
- Not required to have a hard-copy quality manual, records, reports……
- Introduce the laboratory information management system (LIMS)

When Carrying Out Laboratory Activities……

Version 2005: in accordance with stated methods and customers' requirements

Version 2017: in such a way as to meet the requirements of ISO/IEC 17025, the laboratory's customers, regulatory authorities and organizations providing recognition (e.g. accreditation bodies)

Actions to address risks and opportunities

Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity

Examples of risk:

- Shortage of manpower/unavailable of equipment
- Impartiality / relationship with customers / shortcut
- Security of samples
- Trend of quality control fall outside of specified criteria
- Loss of customer
- Occupational health and safety (unavailable of manpower)

Opportunities can arise as a result of a situation favourable to achieving an intended result

Examples of Opportunities:

- New test standard
- New customer

NO requirement for formal methods for risk management or a documented risk management process

Actions taken shall be proportional to the potential impact on the validity of laboratory results

- Don't try use "cannon fire to hit a mosquito"

Introduction of "Risk-based" Thinking

- enabled some reduction in prescriptive requirements
  - "The laboratory shall have procedures……"
- replaced by performance-based requirement
  - emphasis on the results of a process instead of the detailed description of its tasks and steps
  - Rather goal setting approach
  - For example, the laboratory shall control the documents (internal and external) …… (8.3.1)
- Greater flexibility than in 2005 edition in the requirements for processes, procedures, documented information and organizational responsibilities

Procedures Removed from the Latest Edition

- Control of documents (4.3.1)
- Control of records (4.13.1)
- Internal audit (4.14.1)
- Corrective action (4.11.1)
- Calibration of equipment (5.6.1)

Documents Removed from Latest Edition

- master list of document (4.3.2.1)
- training programme (5.2.2)
- register of all subcontractors (4.5.4)
- approved list of supplier (4.6.4)
- job description (5.2.4)
  - The laboratory shall document the competence requirements for each function influencing the results of laboratory activities (ISO 17025: 2017 cl. 6.2.2)

Requirements Removed

- "good housekeeping (5.2.5)"
- "unique identification of equipment (5.5.4)"
- "reference standards of measurements for use in calibration only (5.6.3.1)"
- "preventive action (4.12)"
  - Replaced by "Actions to address risks and opportunities (8.5)"
  - Changed actions from act phase to plan phase

Job Titles Removed from the Latest Edition

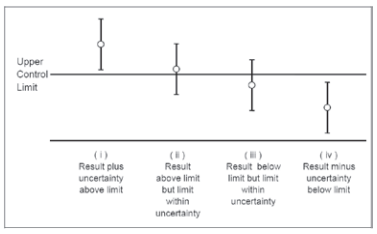
- Removed "quality manager" and "technical management"
- However, shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including (5.6):
  a) implementation, maintenance and improvement of the management system;
  b) identification of deviations from the management system or from the procedures for performing laboratory activities;
  c) initiation of actions to prevent or minimize such deviations;
  d) reporting to laboratory management on the performance of the management system and any need for improvement;
  e) ensuring the effectiveness of laboratory activities.

Laboratory Management

- Change "Top Management" to "Laboratory Management"
  - More suitable for laboratory as part of an organization performing activities other than laboratory activities
- shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of ISO/IEC 17025 (8.2.1)
  - shall address the competence, impartiality and consistent operation of the laboratory
- shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization (8.2.1)

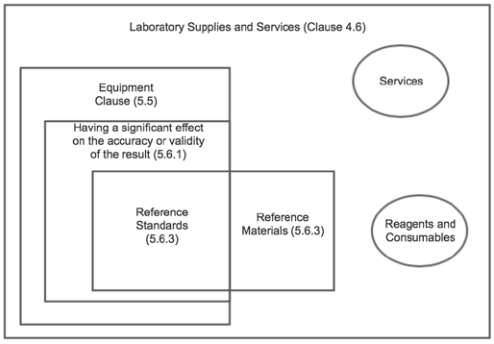
New Requirements

- Range of laboratory activities that conform with ISO/IEC 17025
- Legally enforceable commitments to confidentiality
- Decision rule to consider measurements uncertainty when reporting statements of conformity



- Reason for the change in amendments to reports

Relationships between Equipment, Reference Standards/Materials and Supplies & Services in 2005 Edition



New Definition of Equipment

- including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus
- Those have a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the period of validity
- Records shall be retained for equipment which can influence laboratory activities

Edward Chow
Head of Safety and Quality, Ngong Ping 360

Risk management of Ngong Ping 360

Outline

- Who Am I ?
- What is Ngong Ping 360 ?
- Risk & Risk Management: Some Sharing
- How Risks are Managed in NP360 ?
- Way Forward

2

Who Am I ?

- **Head of Safety & Quality**, Ngong Ping 360 Limited
- Joined MTR in 1990
- Working in safety management (mainly in Auditing !) since 1994
- Seconded to Shenyang MTR Corporation in 2009
- Seconded to Ngong Ping 360 Limited in 2014

- Other Engagements :
  - Honorary Treasurer of Hong Kong Occupational Safety & Health Association
  - Member of OSHC Catering and Tourism Safety & Health Committee
  - Specialist of Occupational Safety & Health Committee, Society of Operations Engineers (Hong Kong Region)
  - Member of Certification Committee, Fugro Certification Service Limited
  - Member of Certification Committee, SMEC Certification Company Limited

3

What is Ngong Ping 360 ?

昂NGONG 坪PING 360
愛上藍・戀上綠
It's blue. It's green. It's love naturally

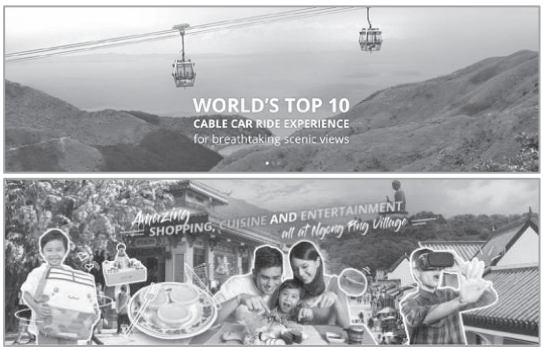
Management System Certification

ISO 9001:2015
Quality

OHSAS 18001:2007
Safety

ISO 55001:2014
Asset

What is Ngong Ping 360 ?



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Risk & Risk Management

What is Risk ?

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Risk Management Process

Source: Scottish Government

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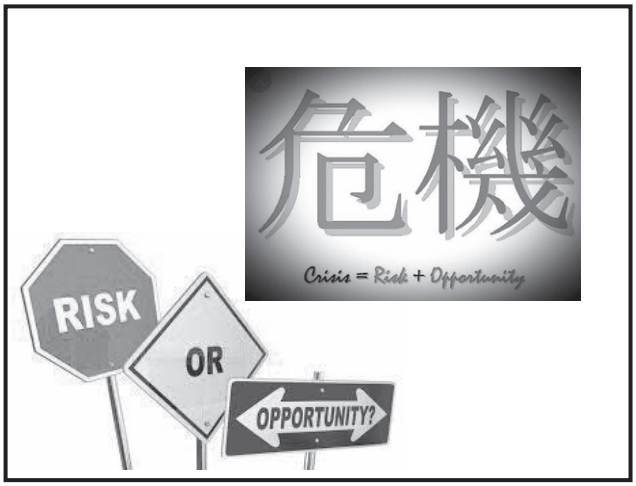
How Risks are Managed in NP360 ?

NP360 Risks

- Operational Risks
- Project Risks
- Enterprise Risks

Way Forward

- Operational Risk
  - Risk Tree Analysis ▸
- Project Risk
  - Marker Cable Replacement Project
- Enterprise Risk: Improvement on Hazard Log ⇨
  - More specificity on additional risk controls, target completion dates for validation and resource required
  - Assessment of effectiveness of risk controls
  - Discussion on forward trends of risks



Thank You

Frank Sheun
QA Manager, Paul Y., Engineering Group

The Backgrounds of ISO9001, Comparison of ISO9001:2008 & ISO9001:2015; and Supply Chain (Export + Import)

HKICA

ISO 9001:2015 Challenges and Opportunities for Auditors
Import/ Export, Plant, Control and Risk Management

Topic : 40 minutes workshop on
1.The Backgrounds of ISO9001, and
2.Comparison of ISO9001:2008 & ISO9001:2015
3.Supply Chain (Export + Import)

Speaker : Frank Sheun

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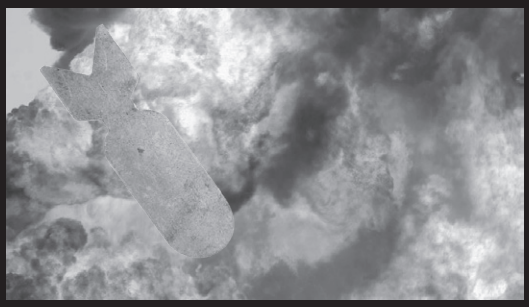
1. BACKGROUNDS OF ISO 9001



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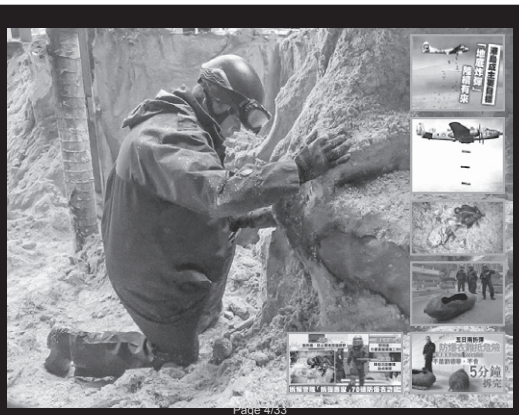

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1.1. INTRODUCTION

- ISO 9000 family of standards have been developed with reference to the production procedure for the manufacturing of military supplies
- All ISO standards are reviewed regularly to make sure they remain relevant to the market via the stages as follows:

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1.2. WHAT IS ISO 9001: 2015

- Based on 7 quality management (QM) principles to set out criteria for a quality management system (QMS) of an organisation, focus on preventing defects instead of fixing them
- Help customers get consistent, good quality products and services, which in turn brings many business benefits to an organisation
- It can be used by any organization, large or small, regardless of its field of activity

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1.3. DEVELOPMENT TIMELINE OF ISO 9001

Version of ISO 9001 Standard	What Has Been Changed
ISO 9001: 1987	ISO adopted BS 5750: 1987 Procedure
ISO 9001: 1994	Documented procedure objective evidence, corrective & preventive action
ISO 9001: 2000	Continual Improvement, 8 management principles and PDCA cycle
ISO 9001: 2008	Minor amendments
ISO 9001: 2015	"Risk Management" and "Organizational Context", etc. introduced

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2. COMPARISON OF ISO9001:2008 & ISO9001:2015

Section	ISO 9001: 2008	ISO 9001: 2015
0	Introduction	✓
1	Scope	✓
2	Normative Ref	✓
3	Terms & Definitions	✓
4	QMS	**4.Context of the Org.**
5	Management	5.Leadership
	Responsibility	**6.Planning**
6	Resource Mgt.	7.Support
7	Product Realisation	8.Operation
8	Measurement, Analysis & Imp.	9.Performance Evaluation
		10.Improvement

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Key Changes in Latest ISO9001: 2015

Key Changes	Why
1. Eight management principles changed to 7	System approach to management combined with process approach
2. Introduce Risk-based thinking	Replace preventive action
3. Increased Emphasis on process approach & PDCA	Together with Risk-based thinking form integral part of new standard
4. Introduce Organisation Context	Know yourself & interested parties for QMS scope/ processes setting

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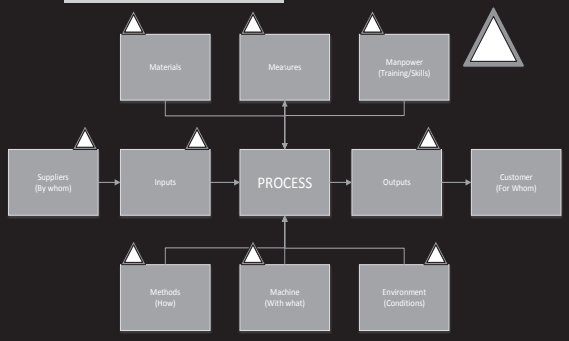
2.1. RISK-BASE THINKING



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2.2. EMPHASIS ON PROCESS APPROACH + PDCA CYCLE

2.2.1.Process Approach

- Structured vertically into a hierarchy of functional units.
- usually focused on the functions only, and
- Horizontal management among functional units and unifying their focus for target.

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Steps in the Process Approach in ISO 9001: 2015

PLAN	
(1) Define: ● context of org. ● scope, obj. & policies of org. ● people or remits who take process ownership & accountability ● the need for documented information ● the interfaces, risks and activities within the process ● the monitoring & measurement requirements ● the resources needed	**(2) Determine:** ● the processes in org. ● the seq. of the processes

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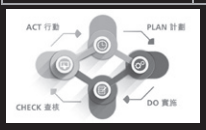
DO	CHECK	ACT
(1) Implement actions needed **(2) Verify the process vs its planned objectives**	**(1) Verify the process against its planned objectives**	**(1) Improvement** ● Change the processes to ensure that they continued to deliver the intended outputs



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2.3. ORGANISATION CONTEXT

Refer to clause 4.1 of the ISO 9001: 2015, an organisation must determine external and internal issues relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its QMS.

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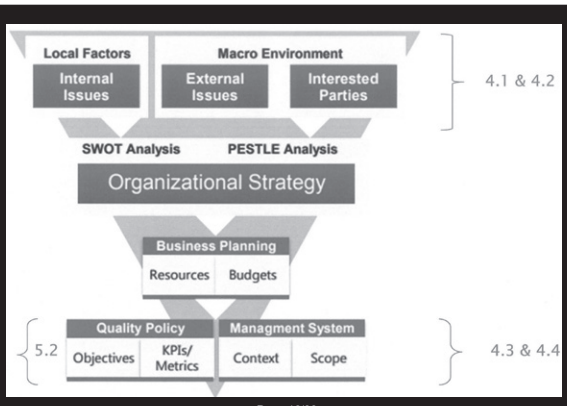

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2.4. MANAGEMENT PRINCIPLES

Since ISO 9001: 2000, the standard requirements have been developed in accordance with 8 management principles, which were for guiding an organisation to improve, these principles are:

Principle 1 – Customer focus
Principle 2 – Leadership
Principle 3 – Involvement of people
Principle 4 – Process approach
Principle 5 – **System approach to management**
Principle 6 – Continual improvement
Principle 7 – Factual approach to decision making
Principle 8 – Mutually beneficial supplier relationships

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Item	Mgt. Principle	Purpose
1	Customer focus	Meet & exceed customer expectations
2	Leadership	Provide objective, direction & engagement
3	Engagement of People	Recognition, empowerment & enhancement of skills & knowledge
4	Process Approach	Understand processes to optimize performance
5	Improvement	Keep performance & create new opportunities
6	Evidence-based Decision Making	Make decision based on analysis from facts, evidences & data
7	Relationship Management	Manage relationship with interested parties to optimize performance

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2.4.1.Customer Focus

ISO 9000: 2005	ISO 9000: 2015
• Organisations depend on their customers & therefore should understand current & future customer needs, should meet customer requirements & strive to exceed customer expectations	• The primary focus of quality management is to meet customer requirements & to strive to exceed customer expectations for sustained success

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2.4.2.Leadership

ISO 9000: 2005	ISO 9000: 2015
• Leaders establish unity of purpose & direction of the organisation & should create & maintain the internal environment in which people can become fully involved in achieving the organisation's objectives.	• Leaders at all levels establish unity of purpose & direction & create conditions in which people are engaged in achieving the organisation's quality objectives

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2.4.3.Engagement of People

ISO 9000: 2005	ISO 9000: 2015
• "Involvement of people", which means people at all levels are the essence of an organisation & their full involvement enables their abilities to be used for the organisation's benefit	• Competent, empowered & engaged people at all levels • Respect & involve people at all levels by recognition of competence

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2.4.4.Process Approach

ISO 9000: 2005	ISO 9000: 2015
• A desired result is achieved more efficiently when activities & related resources are managed as a process	• A QMS consists of interrelated processes which produce results, knowing how these work enable to optimize the system & its performance

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2.4.5.Improvement

ISO 9000: 2005	ISO 9000: 2015
• "Continual improvement" of an organisation's overall performance should be a permanent objective of the organisation	• Improvement is essential for an organisation to maintain current performance levels, to react to changes in its internal & external conditions & to create new opportunities.

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2.4.6.Evidence-based decision making

ISO 9000: 2005	ISO 9000: 2015
• "Factual approach to decision making" means effective decisions are based on the analysis of data & information	• It is important to understand cause & effect relationships & facts, evidence, data & potential unintended consequences analysis lead to greater objectivity & confidence in decision making

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2.4.7.Relationship Management

ISO 9000: 2005	ISO 9000: 2015
● "Mutually beneficial supplier relationships" means an organisation & its suppliers are interdependent & a mutually beneficial relationship enhances the ability of both to create value	● Sustained success is more likely to be achieved when an organisation manages relationships with all of its interested parties to optimize their impact on its performance

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2.4.8.System Approach to Management

ISO 9000: 2005	ISO 9000: 2015
● Identifying, understanding & managing interrelated processes as a system contributes to the organisation's effectiveness and efficiency in achieving its objectives	● Combined with Process Approach

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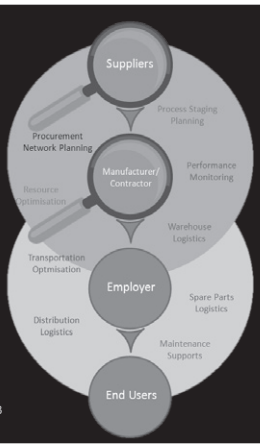
3. SUPPLY CHAIN



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3.1. EXAMPLE - OFF-SITE FABRICATION ITEM

In local Building Construction Industry, some years ago, we have bespoke windows, curtain wall, door, glass-fiber reinforced concrete (GRC), structural steel works and etc. only. However, the trends for using higher percentage of off-site fabrication items, Modular Integrated Construction (MiC) are ever increasing with factors as follows:

- Corporate Social Responsibilities, CSR, and Environmental Protection conscious
- Insufficient skilled labours → expensive
- Time saving for fast track project as works could be done in parallel, and
- Higher quality could be achieved.

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3.2. AUDITOR'S ROLE FOR THESE OFF-SITE WORKS

In order to have "Right First Time" delivery to the building construction project site in Hong Kong, the Main Contractor will have to check the production resources so as to ensure the right items could be timely delivered. Hence, that involves the export & import of supply chain, as most of these off-site works were made outside Hong Kong.

Completed Work → Custom Application for Export → Custom Clearance for Import → Delivery to the site for installation

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For the construction of a temporary structural steelwork in HK as an example, we have audited the following details of the fabricator on weekly basis to ensure "Right 1st Time" delivery:

- Production resources
- QA system
- Fabrication progress
  - ✓ Production records
  - ✓ Welding summary
  - ✓ HOKLAS laboratory prelim. & final reports

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In order to ensure "Right 1st Time", but due to time constraints, we could not carry out physical pre-assembly in workshop, so we have adopted 3D scanning & of the bridge components and verified that all bridge components are within assembly tolerance.

Hence, "Right First Time" has been successfully achieved.

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

Practice and Experience of Auditors – corporate management risk for Export/Import, Plant and Control

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

Collaborating Organizations :

ISO9001:2015 Challenges and Opportunities for Auditors
Import/Export, Plant, Control and Risk Management

Practice and Experience of Auditors
Corporate Management Risk for Expert/Import, Plant and Control

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香港專業審核師學會主席

16 August 2018, Regal Riverside Hotel (Hong Kong) 1

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

Content

- Cap. 60 Import and Export Ordinance
- Internal Compliance Programmes for the Import/Export Industry
- Guidance Note on Company's Internal Control Programme
- Model Internal Control Programme (ICP)
- Conclusions

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Cap. 60 IMPORT AND EXPORT ORDINANCE

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The Hong Kong Special Administrative Region (HKSAR) implements a comprehensive and stringent control over the import and export of strategic commodities to prevent HKSAR from being used as a conduit for the proliferation of weapons of mass destruction, while at the same time to ensure the free flow of advanced technology for legitimate commercial, industrial and research use.

The Customs and Excise Department is the sole enforcement agency for strategic trade controls. It is mainly responsible for:

- physical examination of imported and exported cargoes;
- checking of import and export licences to verify the authenticity of information provided therein;
- collection and collation of information and intelligence; and
- investigation and prosecution of contravention of controls.

Types
Strategic commodities are specified in the Schedules 1, 2 and 3 to the Import and Export (Strategic Commodities) Regulations, Chapter 60G,Laws of Hong Kong.

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Recent Cases Highlight Under the Strategic Commodities Control List
Systems / Equipment / Integrated Circuits for Information Security (5A002)

- On 7 March 2018, a local trader was fined HK$62,000 for importing 57 pieces of digital signal processors [Cat. 3A001(a)(2)(c)] to Korea not under and in accordance with a licence.
- On 4 December 2017, a local trader was fined HK$55,000 for exporting 26,000 pieces of integrated circuits [Cat. 5A002] to Mainland China not under and in accordance with a licence.
- On 18 September 2017, a local trader was fined HK$50,000 for importing 1 set of electronic streak camera system [Cat. 6A203] and components [Cat. 3A230] from USA not under and in accordance with a licence. The offending goods, in value of HK$257,495 were forfeited.
- On 30 August 2017, a local trader was fined HK$100,000 for exporting 29 pieces of integrated circuit [Cat. 3A001(a)(2)(c)] to Mainland China not under and in accordance with a licence.
- On 13 April 2017, a local airline and a local logistic company were fined a total of HK$108,000 for exporting 119 pieces of WLAN Access point [Cat. 5A002] to USA not under and in accordance with a licence.
- On 21 December 2016, a local logistic company was fined HK$30,000 for importing 63 pieces of assorted computer parts and network equipment [Cat. 5A002] from Czech Republic not under and in accordance with a licence. The offending goods, in value of HK$256,175 were forfeited.

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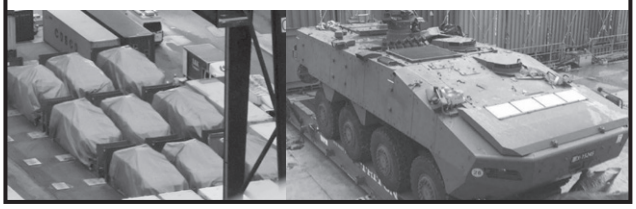
- Hong Kong's biggest seizure of "strategic commodities" in two decades.
- Nine armoured vehicles were uncovered by Hong Kong customs on January 2017 in containers without the required permits.
- The vehicles, which were not "specifically" declared in the cargo manifest.



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Internal Compliance Programmes for [the Import/Export Industry]

Since Hong Kong is a major international commercial and trading centre through which large quantity of high technology goods are imported and exported everyday, traders must share responsibility in ensuring that goods passing through Hong Kong complies with the internal compliance programme of *Strategic Commodities Control System* of Trade and Industry Department, HKSAR:

Guidance Note on Company's Internal Control Programme
Core Elements of A Company's Internal Control Programme

For import/export industry, all companies have an obligation to strictly comply with the Laws of different countries. Therefore, *ICP shall be integrated into* the quality management system and company's code of practice.

Ref: Advice for Internal Compliance Programmes, Trade and Industry Department, HKSAR 6

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Internal Compliance Programmes for [the Import/Export Industry]

The establishment of an effective internal compliance programme, or Code of Practice, provides companies with a method of routinely screening transactions in order to eliminate suspicious approaches, thereby ensuring that only legitimate business transactions proceed and the risk of breaching the law in this area is minimized.

- ✓ An internal compliance programme involves a company's commitment that its products will not be diverted
- ✓ Implementation of an effective internal compliance programme is necessary

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ISO 9001:2015 Contents

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1. Scope 2. Normative references 3. Terms and definitions

4. Context of the organization
- Understanding the organization and its context
- Understanding the needs and expectations of interested parties
- Determining the scope Of QMS
- Quality management system and its processes

5. Leadership
- Leadership and commitment
- Quality Policy
- Organizational roles, responsibilities and authorities

6. Planning
- Actions to address risks and opportunities
- Quality objectives and planning to achieve them
- Planning of changes

7. Support
- Resources - Organizational knowledge
- Competence
- Awareness
- Communication
- Documented information

8. Operation
- Operational planning and control
- Requirements for products and services
- Design and development of products and services
- Control of externally provided processes, products and services
- Production and service provision - Post Delivery, Control of change
- Release of products and services
- Control of nonconforming outputs

9. Performance evaluation
- Monitoring, measurement, analysis and evaluation
- Internal audit
- Management review

10. Improvement
- General
- Nonconformity and corrective action
- Continual improvement

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Terms/Names

"air consignment note (航空托運單)
"air waybill (空運提單)
"air transhipment cargo (航空轉運貨物)
"article in transit" (過境物品)
"bill of lading" (提單)
"manifest" (艙單)
"cargo" (貨物)
"transhipment cargo" (轉運貨物)
"unmanifested cargo" (未列艙單貨物)
"contraband" (違禁品)
"prohibited article" (禁運物品)
"consign" (托運)
"appointed officer" (獲委任人員)
"authorized officer" (獲授權人員)
"owner" (擁有人)
"specified agent" (指明代理人)
"specified body" (指明團體)
"validated production notification" (認可生產通知書)
"import" (進口、輸入)
"licence" (許可證)
"production notification" (生產通知書)
"reference number" (編號)
"security device" (保安裝置)
"smuggling" (走私)

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Guidance Note on Company's Internal Control Programme

Model Internal Control Programme (ICP)

A number of elements that are crucial components and will be found in one form or another in all effective ICPs :

1. Policy Commitment to Compliance
2. Nomination of Responsible Personnel for Import/Export Controls
3. Procedures Related to Trade Controls
4. Shipment Control
5. Internal Audits
6. Education and Training
7. Record Keeping
8. Guidance to Subsidiaries or Affiliates (if applicable)
9. Obligation to Report and Penalties
10. Interaction with the Trade and Industry Department
11. Integration with Quality Management Practices

https://www.stc.tid.gov.hk/english/hksarsys/files/icp_revised.pdf

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Why do companies have a need for *Internal Control Programme* ?

- Rapid development of high-technology and growth in demand
- Compliance with Hong Kong laws
- Meeting international control requirements
- Assurance on management and ethical standards

What does an effective ICP provide?

Systematic screening for transactions so as to ensure that only legitimate business transactions would proceed

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(1) Policy Commitment to Compliance

State a firm commitment in writing that:

- Not having its products used for WMD [weapons of mass destruction] and other problematic purposes
- Fully comply with the Laws of Hong Kong
- Seek endorsement from senior management and bring attention to all employees and customers

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(2) Nomination of Responsible Personnel

- To avoid conflict of interest, officers with primary responsibility for trade control matters should be independent from the sales/ marketing department
- Decision should NOT be managed by a single individual

Responsibilities and authority for the trade control team and Trade Control Manager (TCM) must be clearly defined. Duties include:

- creation, revision and implementation of the ICP;
- creation, revision and implementation of operating procedures (detailed regulations) to carry out the ICP;
- screening and approval of all transactions and enquiries as to product, end use, end user, customers and the transaction viewed as a whole;
- trade control-related audits;
- training and education of staff regarding trade controls, including courses, on-the-job training and provision of information; and
- guidance and assistance to subsidiaries and affiliates, if any.

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(3) Procedures Related to Trade Controls

[ISO: to conform to their requirements are identified and controlled to prevent their unintended use or delivery]

A. Product Screening
B. Customer and end user Screening
C. End-use Screening
D. Transaction Screening
E. Application for Licences

Note: All screening processes must be conducted before the order is accepted.

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3A. Product Screening (I)

- To conduct a general screening in advance instead of screening each transaction
- To evaluate and clarify all goods by the trade control team together with the engineering/technical department; or
- To request a determination from the supplier of the goods; or
- To use the pre-classification service by forwarding the technical details to the Classification Section of TID

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3A. Product Screening (II)

- To keep records or lists of the details of the products, including the name, brand, model, product no. and the part of the Import and Export (Strategic Commodities) Regulations control list it falls under
- Sales/Marketing department to use the lists to check against the order received, to request determination from the trade control team if in doubt

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3B. Customer and End User Screening (I)

Parties

The trade control team will need to classify all customers of the company according to the risk they may be involved or may present a risk that goods supplied to them are diverted to such a programme [e.g. WMD, weapons of mass destruction]

- To visit websites of Governments of some high-tech supplier countries
- To maintain the lists of problematic/concerned entities
- To check against the lists upon receipt of an enquiry or order from customers

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3B. Customer and End User Screening (II)

To confirm the customers and end users/companies/entities by checking their

- address (post office box address should not be accepted!)
- contact no.
- business registration details
- other relevant information

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3B. Customer and End User Screening (III)

Destination Screening for Re-exports

- To ensure the original exporting country/place has no objection to the goods being re-exported to the destination
- To get copies of valid export licences or other requisite documents issued by the original exporting country/place, if necessary
- To compile and maintain lists of allowable re-export destinations for each different product in advance
- To check each re-export against the lists

3C. End Use Screening

- To ascertain the end use of the product from the customer

  e.g. For what purpose the product is required?
  How will it be used at the final destination?

- To stop further transaction with the customer/ end user if the intended end use is suspicious

  e.g. related to the development, production or use of WMD programme or any illegal weaponry activities

3D. Transaction Screening

- To review the proposed transaction as a whole and all relevant information received from customers and end users

  e.g. Any likelihood of false information to conceal a WMD-purpose?

- To request contractual assurance from customers

3E. Applications for Licenses

- To apply licence [from TID] for shipping controlled strategic commodities to/from Hong Kong
- To obtain relevant documents to support the application

(4) Shipment Control

Companies must ensure that the goods actually imported or exported match with the relevant shipping documents.

To halt the shipment and inform the trade control team immediately if discrepancy between the documents and the shipment is found

(5) Internal Audits

The trade control team should conduct compliance audit or review the related functions on a periodic basis.

- To establish regular programme of internal audits
- To appoint impartial auditors
- To keep the audit result and relevant documents
  - In large companies it may be feasible to establish an audit section within the trade control team. Otherwise the audits could be conducted by the TCM.
  - If necessary the audit could also be performed by another group within the company.
  - In all cases, the auditor be completely unrelated to the team/department being audited.

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(6)Education and Training

To conduct regular training for employees engaging in import and export of strategic commodities

To keep the training records on the dates, the names of attendees, the subjects, etc.

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(7) Record Keeping

To maintain records of all paperwork in relation to a particular transaction or enquiries relevant to the Import and Export (Strategic Commodities) Regulations.

e.g. business transaction documents (order forms, contracts, invoices, bills of lading, air waybills, etc),
screening/ trade control documents (verification on the end user, copies of import/export licenses, etc)

(8) Guidance to Subsidiaries and Affiliates

Parent company should provide guidance on trade control practices to its subsidiary or affiliate on implementing ICP.

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(9) Obligation to Report any Violations of the law

- Involvement of all employees of the company
- A clear procedure for reporting any violation of Regulations or perceived risk of violation to the trade control team
- The trade control team is responsible for investigating the report
- Corrective actions or reminders should be issued to all relevant staff
- For cases involving violation of the Import and Export (Strategic Commodities) Regulations, it must be reported to TID

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Conclusion : Integration with Quality Management Practices

- An effective ICP should be adopted as part of the company's code of practice that aims at activity of a high ethical and commercial quality and standard
- The company should ensure that the procedures for screening transactions and ensuring compliance with the Import and Export Ordinance and law [Import and Export
- (Strategic Commodities)]
- Employees should demonstrate familiarity with and commitment to trade control compliance issues and practices.

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Collaborating Organizations :

ISO9001:2015 Challenges and Opportunities for Auditors
Import/Export, Plant, Control and Risk Management

Practice and Experience of Auditors
Corporate Management Risk for Expert/Import, Plant and Control

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THANK YOU

16 August 2018, Regal Riverside Hotel (Hong Kong)

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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.

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