

Reprocessing of Medical Devices: What is our current practice?

Commissioned Training of Disinfection and Sterilization (27-29 Feb)
Chief Infection Control Office
28 Feb 2012

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Topic

1. History of Sterilization Service in Hong Kong
2. Reprocessing centre
3. Method of Decontamination
4. Risk Management on Reuse Single Used Medical Device (SUD)
5. Decontamination Standard in Hong Kong
6. Training and development
7. Service gap analysis
8. NTWC CSSD service model in decontamination service
9. Way forward

(1) History of Sterilization Service in Hong Kong

History of Sterilization Service in Hong Kong

- Central Sterile Service Department (CSSD) was managed by Pharmacist since the establishment of hospital services
- Since 1973, nursing staff took over the management of CSSD in various regional Hospital (QEH, QMH, PMH and PWH)
- Before 70 century, CSSD mainly reprocessed sterile reusable medical devices, like syringe and needle, intravenous set, linen gown & drape, surgical glove and dressing set etc.

History of Sterilization Service in Hong Kong

- Nowadays, sterile commercial products are available in the market
- Some CSSDs are still responsible to purchase and supply sterile syringe & needle, sterile gloves, Intravenous set
- CSSD focuses on the supply sterile linen pack to operating theatre and supplies sterile ward procedure set to ward and clinical area
- Theatre Sterile Supply Unit (TSSU) concentrates on reprocessing of surgical instrument for surgical operation

History of Sterilization Service in Hong Kong

- Since **1998**, CSSD of Tseung Kwan O Hospital CSSD combined the CSSD & TSSU service
- Kowloon West Cluster: Centralized CSSD in Lai King Block, it served **7 hospitals** in the cluster, which are KWH, PMH, CMC, YCH, KCH, OLMH, WTS since 2004
- It mainly provided sterile set to ward and clinical areas and provided sterile operation linen packs to operating theatre. However, the OT of these hospitals have reprocess their own OT surgical instruments

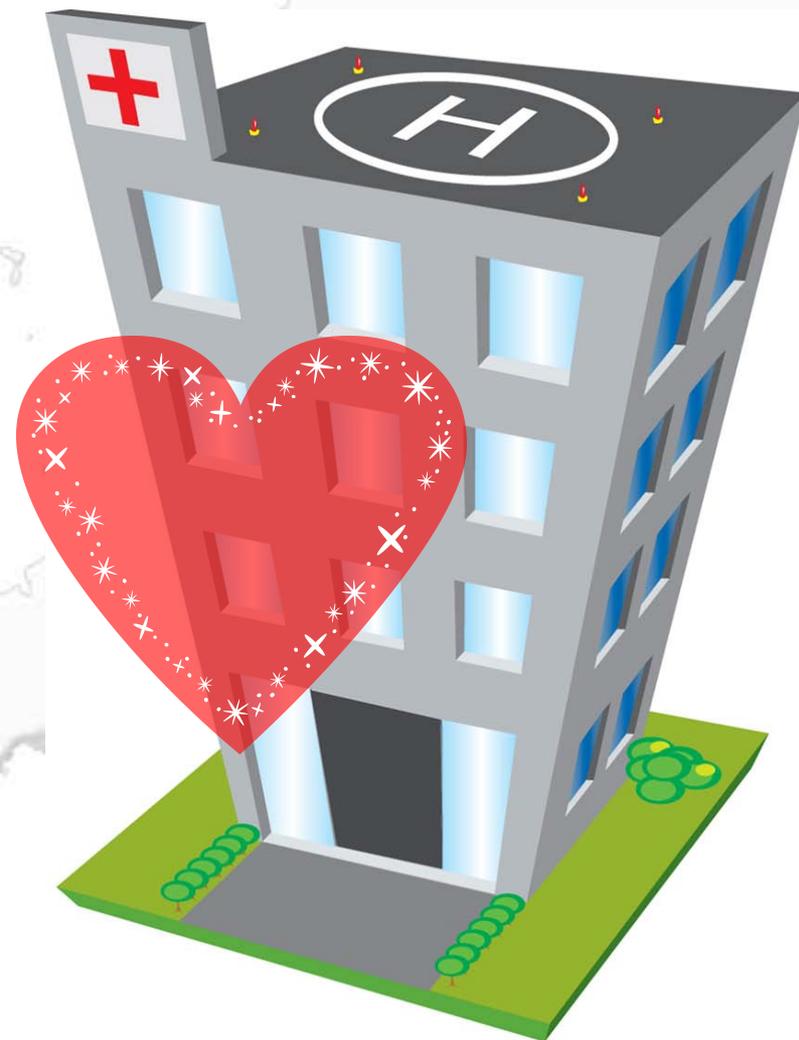
(2) Reprocessing Centre

- CSSD
- TSSU
- Electro-Medical Diagnostic Unit (EDU)
- Satellite reprocessing centres in various clinical area, eg. OT, ICU, ward, clinic

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CSSD

Heart of Hospital



CSSD

Customers: wards, clinical areas and operating theatre

- focus on supply of CSSD product including sterile **ward procedure set**
- Procure and supply of sterile products originally produced in CSSD eg. **surgical gloves, intravenous set etc**
- supply surgical linen drape and gown to operating theatre

Scope of CSSD Service

Sterile Theatre Linen Drape



Scope of CSSD Service

Sterile Ward Procedure Set



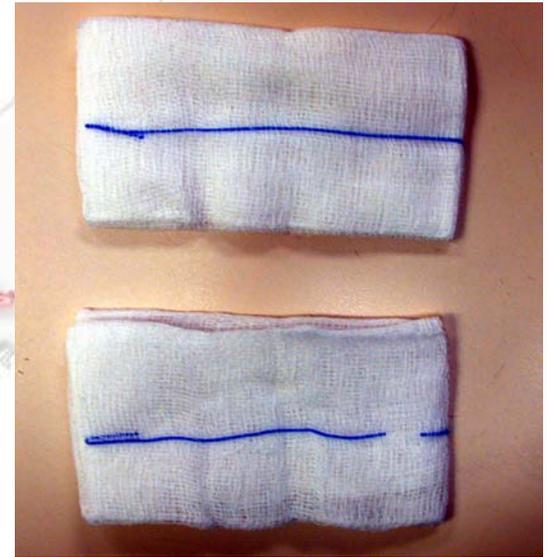
Sterile Supplementary Instrument Packet

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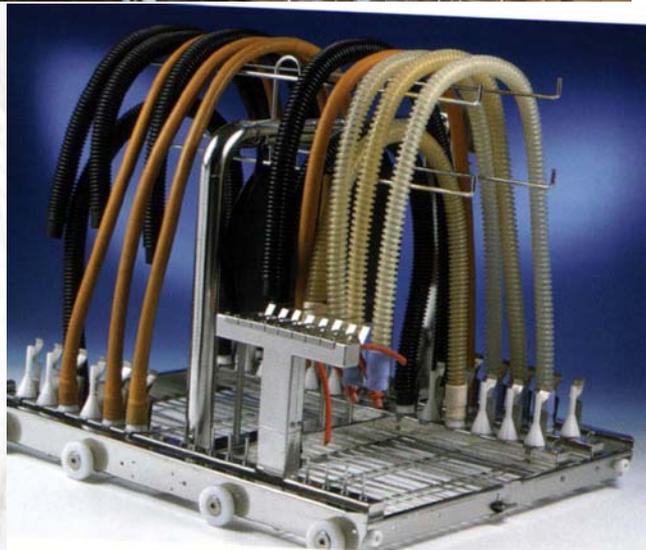
Scope of CSSD Service

Sterile Dressing Packets



Scope of CSSD Service

Thermal Disinfection of Plastic Utensils & Tubing



Scope of CSSD Service

To reprocess user-owned reusable medical devices



Scope of CSSD Service

Supply Sterile Commercial Consumables



TSSU

Customer: Operation Theater (OT)

- Reprocessing surgical instrument
- Fiber-optic endoscope

Remark: Some hospitals in Hong Kong do not have a centralized reprocessing centre. The surgical instrument are sterilized using manual washing and flash Sterilization

Scope of TSSU Service

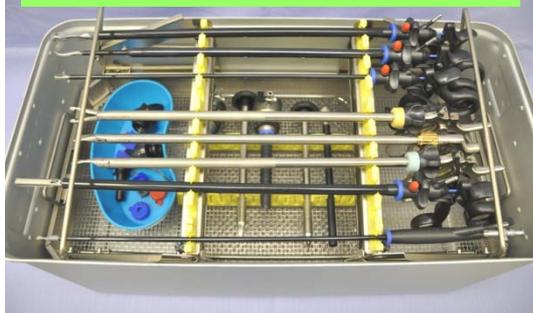
Focus on surgical implant and instrument



Scope of TSSU Service

Reprocessing surgical instrument and utensils

Extra Surgical lap.



Basic set



Basic Surgical lap



Surgical Major Set



Major Utensil



Endoscopic Unit

- Reprocessing fiber-optic endoscopy and accessory at point of use
- Manual or Automatic

ASP
CIDEX TRAYS

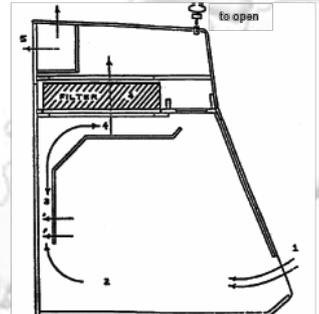


Figure 2—A ductless fume hood showing the airflow pattern. As air is drawn into the hood from the room (1), a horizontal air stream (2) removes contaminants from the work surface to the rear (3) of the fume hood. The air is channeled up and into the filter beds (4). Clean, filtered air is exhausted for recirculation (5).



Satellite reprocessing in various ward, clinic

- Department owned medical devices
- Disinfect and sterile medical device locally for their own used
- CIDEX without close system

ASP
CIDEX[®] OPA



ASP
CIDEX[®]



(3) Method of Decontamination

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Washer disinfector



Thermal Disinfection (Mechanical Wash)



Introduction of Tunnel Washer



Steam Sterilization



Low Temperature Sterilization

Hydrogen peroxide STERRAD® 100NX™ System



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Only 2 Ethylene Oxide sterilizers in HA

Endoscopic Instrument



Automatic Endoscopic Reprocessor



Table top autoclave & Chemical Disinfectant


CIDEX[®] OPA



(4) Risk Management on Reuse Single Used Medical Device (SUD)

Risk Management on Reuse Single Used Medical Device (SUD)



With balloon, water trapped in balloon after cleansing and disinfection



Risk Management on Reuse Single Used Medical Device (SUD)

- HA Governance - Quality & Risk Management
- Major objective – develop a systemic framework to reduce the risk of reuse
- Develop guideline or policy to assure standard of practice
- Train frontlines colleagues to familiar with the new system
- Develop Central List with standardized name

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Risk Management on Reuse Single Used Medical Device (SUD)

- Set priority of SUD by specialty according to the practical experience of nurses and doctor with consideration of potential risk factors
- Initiate bulk purchase to trim down the operational cost
- Conduct audit with improvement recommendation to pressurize authority to allocate extra resources in fading out SUD based on priority
- Faded out SUD based on risk factors

Risk Stratification

FDA and Spaulding Classification

		Spaulding Classification		
		Non-critical	Semi-Critical	Critical
FDA Class	Class I	Very low risk	Low risk	Moderate risk
	Class II	Low risk	Moderate risk	Moderate-high risk
	Class III	No such item	High risk	High risk

MILESTONE OF REUSE SUD IN HK

Jun 04	Develop a registration system for reuse SUD
Oct 04	Completed pilot registration project in major users (operating theatre, Electro-diagnostic Unit, Cardiac Catherization unit) in TMH and PYNEH
Nov 04	Conducted internal audit to assure compliance in Tuen Mun Hospital
Dec 04	Finalized report and recommendation of the pilot study

MILESTONE OF REUSE SUD IN HK

25 Jan 05	Rolled out registration to other hospitals
Dec 05	Formation of Advisory Group in Head office
9 Mar 06	Clarification of personal liability of staff who manage reuse SUD. Insurance covers the liability risk
19 Apr 06	Launch corporate guidelines

MILESTONE OF REUSE SUD IN HK

17 Jul 06	Opened corporate forum to introduce the registration system
Aug 07	Initiated corporate registration of all reuse SUDs in all departments among all Hong Kong public hospitals
Aug 07	HKW established cluster expert group to visit user dept to review their practice
Jan 08	Develop of criteria for risk priority in order to phase out high risk SUDs

Risk Factors for Prioritization of the SUD for Fading out

Risk – Product Design

- ✦ The lengths is longer than 1 meter
- ✦ The lumen is narrower than 2 mm in diameter
- ✦ Device with multi-lumen, closed end lumen or twisted lumen
- ✦ Device with multiple joints or movable parts
- ✦ Device with balloon
- ✦ Device with lumen containing bladed or coiled wire
- ✦ Device with constraint in reprocessing



MILESTONE OF REUSE SUD IN HK

18 Jun 08	Conducted corporate-wide audit by corporate audit team
Sep 08	Published of the first corporate internal audit report : Management of Single Use Medical Device
Apr 09	CE HA allocated XX millions to 7 cluster hospitals to phase out 8% of high risk SUDs

Internal Audit Report

Internal Audit:

Management of
Single Use (Medical)
Devices (SUDs)

Audit Team

Po Yu Chan
Cecilia Yeung
Rob Burns

September 2008



MILESTONE OF REUSE SUD IN HK

2010/2011	To develop a database computer system to manage the SUD registration and develop central list and assign unique code to each cluster SUD
Sep 10	Hospital Authority Head Office stopped registration of new SUD. Clinical department should include extra SUD budget for new services.
Jan 11	Hospital Authority Head Office published the first corporate policy on SUD
Apr 11	Hospital Authority Head Office allocated over XXM to phase out over 60 item of SUD

SUD Policy

 醫院管理局 HOSPITAL AUTHORITY	Patient Safety & Risk Management Department	Doc. No.	PSRM-PY-5
		Version	V1
	HA Policy on Single Use Devices	Page	1 of 9
		Effective date	18 Jan 2011

1 Title

HA Policy on Single Use Devices (SUD)

2 Purpose

Hospital Authority (HA) intends to phase out the reuse of SUD by stages. The hospitals are allowed to reprocess selected SUD **ONLY** when strict reprocessing procedures are followed (Para. 7). This set of policy aim at assuring the safe reuse of SUD and specifying the general principles for clusters to develop their own operational instructions appropriate to their clinical settings.

3 Scope

A SUD is a disposable device intended to be used on one patient during a single



(5) Decontamination Standard in Hong Kong

Decontamination Standard in HK

- Decontamination manager adopted **various international standard**
- Validation of decontamination machine is limited
- Only routine tests were performed to assure decontamination quality

For example

- Chemical indicator
- Bowie & Dick Test
- Biological indicator

Spaulding Classification

Non-critical	topical contact and not penetrate intact skin Thorough cleansing Low level disinfection
Semi-critical	Contact intact mucous membranes and not penetrate normally sterile areas of the body High-level Disinfection / sterilization (thermal disinfection)
Critical	Contact normally sterile tissue or body spaces Sterilization

Bowie Dick Test for steam sterilization

How to Read a 3M™ Comply™ Bowie-Dick Plus Test Pack

Pass:
 No Air Leaks.
 Both tests show good vacuum efficiency. Early Warning Test Sheet indicator spot is black.

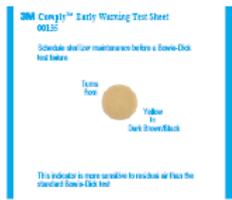


Pass:
 Extra-sensitive Early Warning Test Sheet indicator spot is dark brown, showing reduced vacuum efficiency. Bowie-Dick Test Sheet shows acceptable result.

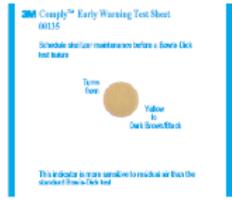


Schedule repairs now to avoid mandatory shutdown when you least expect it.

Fail:
 Bowie-Dick and Early Warning Test Sheets reveal that sterilizer shutdown is necessary.



Fail:
 Bowie-Dick and Early Warning Test Sheets indicate that significant air is present.



Rest

Compact-PCD[®]s for the Bowie-Dick-Simulation-Test and the Batch Monitoring System



Performance qualification- Verification of cleansing

Routine testing



Soil Test

MEDIZIN



Example: Sweden (Annex M)

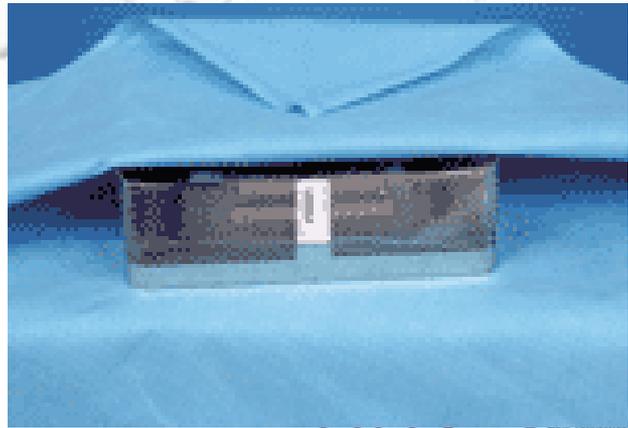


Decontamination Standard in HK

- ANSI/AAMI ST 58: 2010
- ANSI/AAMI ST79:2010
- AS NZ 4187: 2003
- EN 285
- EN 868
- HA intranet
- Health Building Note 13
- HTM 2010
- HTM 2030
- ISO 11607
- ISO 13485
- ISO 14937
- ISO 15883
- ISO 17665

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Standard Packaging Material



Linen Wrapper



Decontamination Standard in Hong Kong

- It varies a lot from cluster to cluster, from hospital to hospital
- Flash sterilization as routine practice
- Satellite reprocessing centres
- Adopt different international standard in daily practice
- Perform routine test to assure sterility quality

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(6) Training and Development

Training and development

- ✚ Before 1991 Hospital Authority: Overseas training (UK)

Operation Management :

- Standardization
- Quality Control
- Material Management
- Inventory Management

- ✚ In 1991, Hospital Authority is established for managing the public health care system in HK

- Cost consciousness
- Risk Management
- Service quality
- Continue Quality Improvement

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Training and development

- Hong Kong Sterile Service Management Association (HKSSMA) is established on 1997
- A local professional association in decontamination practice
- Basic training annually
- Organize 3 - 4 seminars / year

Training and development

- Hospital Authority
- First formal commissioned training on sterilization service on Sept, 2011
- Overseas Training in Health Care Science Limited in UK x 4 nurses in Nov 2011
- Second commission training of sterilization service in Jan, 2012
- Overseas Training in Eastwood Park, UK x 4 nurses in Feb 2012

(7) Service Gap Analysis

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ACHS Accreditation

- The Australian Council on Healthcare Standards (ACHS) conducted accreditation exercise locally in 2010
- A Gap analysis was performed to identify the quality gap of CSSD

HA Report

Issues identified

- Routine use of flash sterilization
- No clear demarcation of clean & dirty zone
- Lack of tracking & tracing system
- Governance structure deficiency

(HA intranet)

Flash Sterilization

- Annual Plan:
 - Sterilization Enhancement Program
 - Eliminate the use of Flash sterilization

Governance

- Strengthen governance structure
 - Corporate-wide
 - Cluster-wide
 - Hospital-wide

Key Objective 2: Improve Continuously Service Quality and Safety

Our service priorities for 2011-12

- Strengthen safety culture and risk management
- Enhance quality systems and clinical governance
- Reconfigure services and promote timely intervention

ACTION

TARGET

Strengthen safety culture and risk management

Enhance drug safety in aseptic dispensing service by centralizing high risk preparations such as intrathecal injections, epidural injections and biological preparations at pharmacy operated aseptic dispensing units	Upgrade some of the existing aseptic dispensing suites and expand the central pharmacy aseptic dispensing service to cover high risk preparations by 1Q12
Ensure safety and quality of pharmacy service in GOPCs by expanding pharmacist coverage at clinic pharmacies during clinic operating hours	Expand the existing pharmacist coverage in GOPC pharmacies by 1Q12
Provide clinical pharmacists at treatment sites of chemotherapy service to enhance drug safety	Extend the program, which is being piloted in KWC and NTWC, to all clusters by 1Q12
Eliminate the use of FLASH sterilization methods in surgical operations and enhance sterilization service for operating theatres to align with international standards	Implement a sterilization enhancement program for operating theatres in QMH, QEH, TMH, YCH and CMC by 1Q12
Continue to implement measures to reduce the re-use of Single Use Devices (SUD)	Phase out the re-use of 5% of class II critical (moderate to high risk) SUDs by 1Q12
Enhance the quality of blood products provided by the blood transfusion service	Increase the supply of leucofiltered red blood cells by 45,000 units by 1Q12
Strengthen patient safety culture, situational awareness, team communication and speak-up culture using Crew Resource Management (CRM) training adapted from the aviation industry	Commence a 3-year CRM training program in two acute hospitals by 1Q12

Clear demarcation of clean and dirty area

- Engineering approach
- May be adopted during renovation
- Purposely built a mega centre

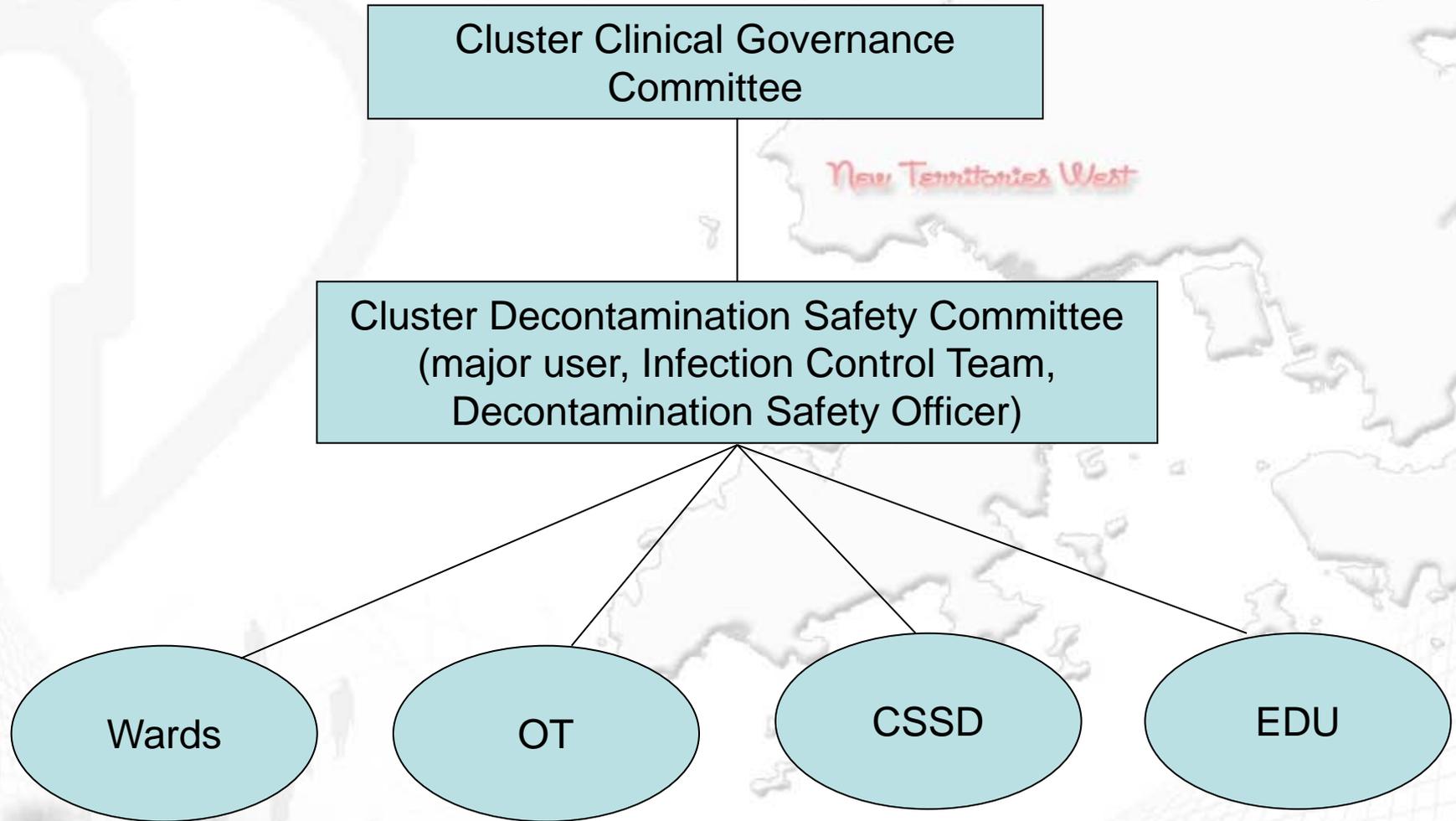
Corporate Electronic System

- Development of Tracking and Tracing System



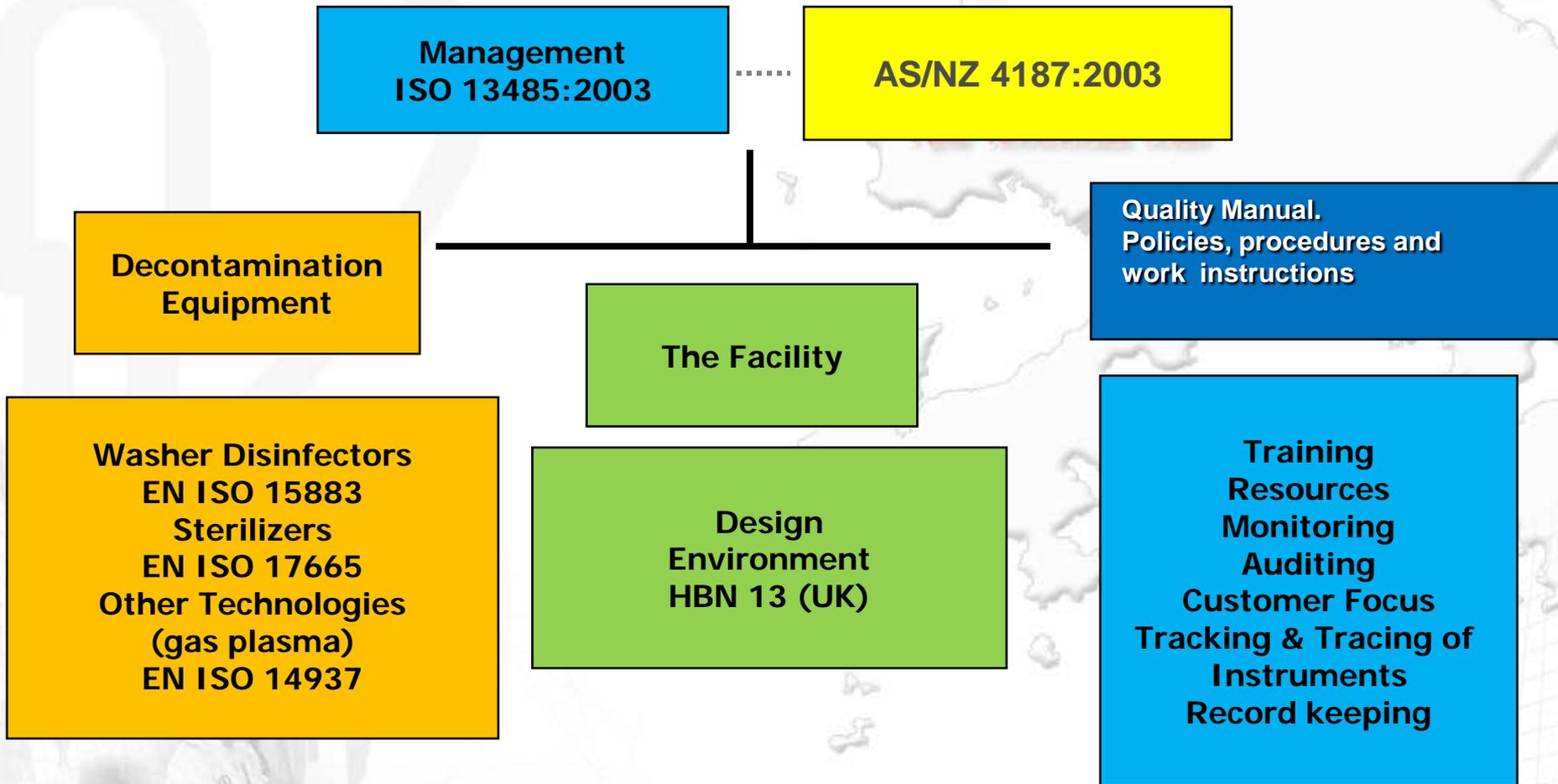
(8) NTWC CSSD service model in decontamination service

Governance Structure of Decontamination Practice in NTWC



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Quality Management System



Conversion CSSD to TSSU/CSSD

- Revamp the scope of CSSD service
- Fade out non value-added service provided by CSSD
- Re-built a new CSSD with advanced instrumentation
- Eliminate flash sterilization for all elective surgical instrument
- Centralized decontamination service

Phase out all linen items

- ✦ To phase out all linen items by disposable drapes including OT linen and linen wrapper towels.



Changes of ward procedure set

- ✦ To convert the ward procedure set by supplying stainless steel instrument peelable pouches
- ✦ Use disposable ward dressing set and the peelable pouches instead.



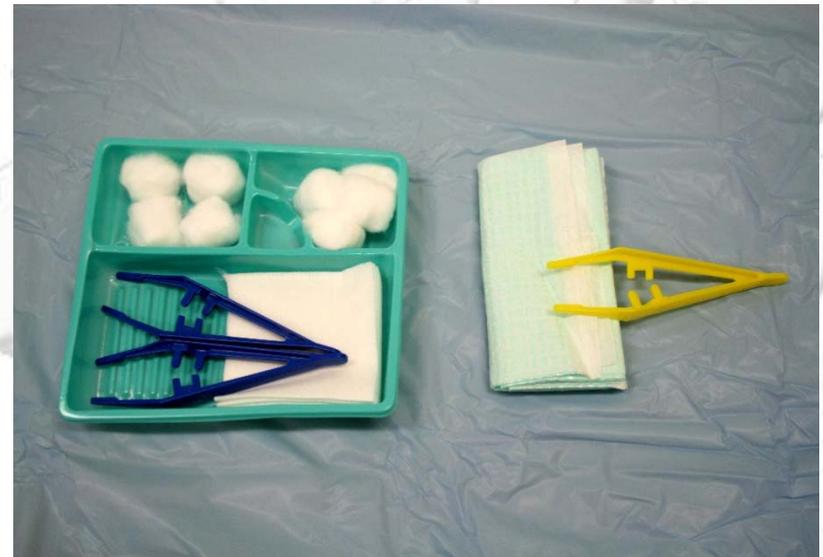
Example: S17 Suture Set

– only provide instrument packet



Changes of ward procedure set

All ward procedure sets were replaced by a basic pack (S25E), the set contents (instruments) will be supplied as an individual packs.



Sterile Supplementary Utensils

Tray



Kidney Dish



Bowl

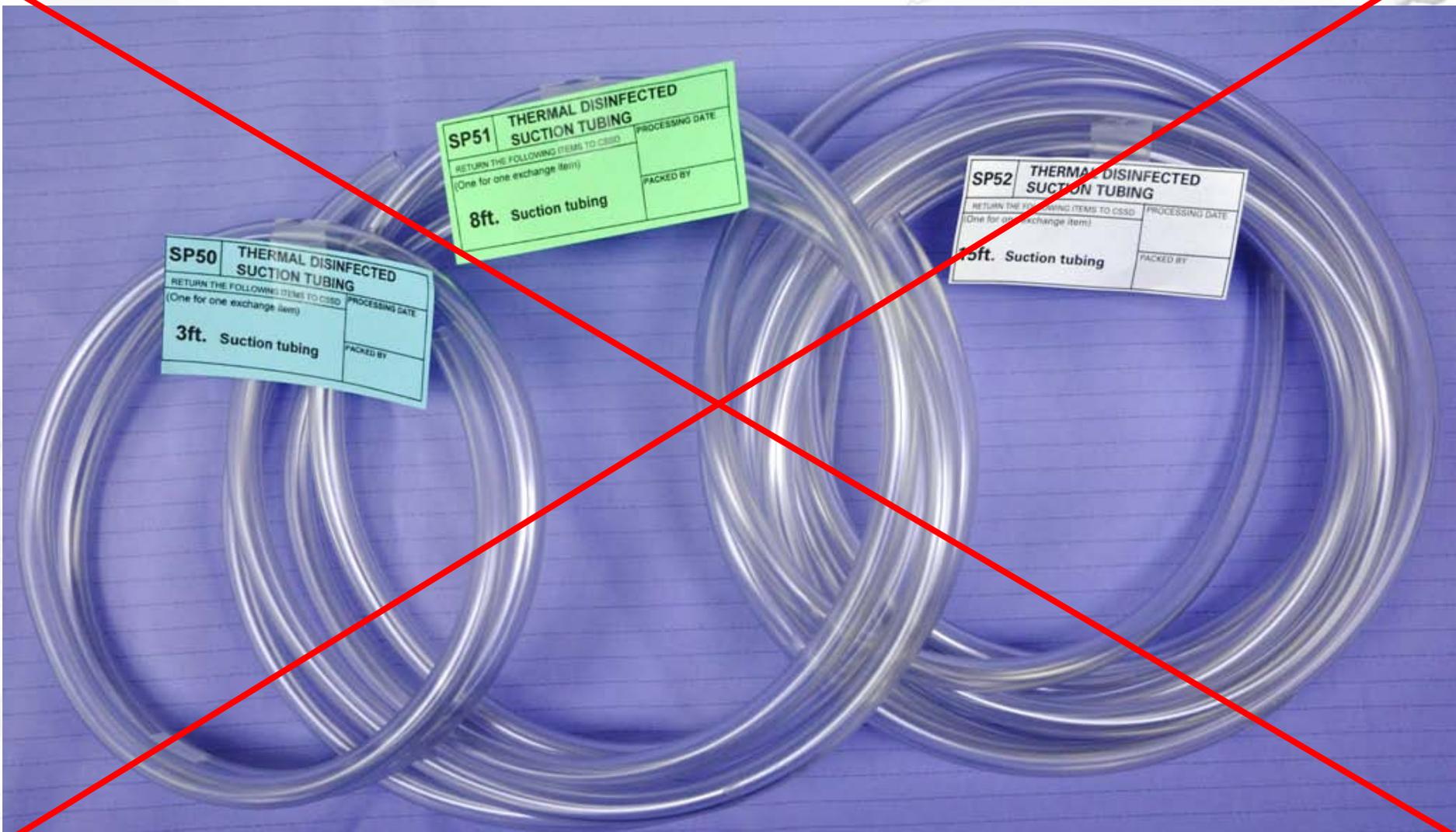


Use of disposable dressing items

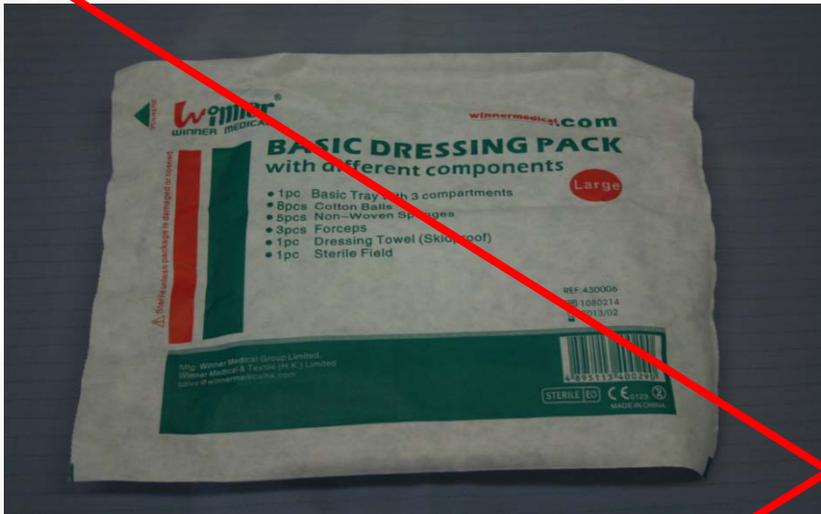
✚ Phase out dressing item. Use pre-sterile ones



Cease reprocessing of single use respiratory tubing and suction tubing



Handover the pre-sterile consumable to Hospital Store



Auto-Refill System

Check any Items insufficient in Qty

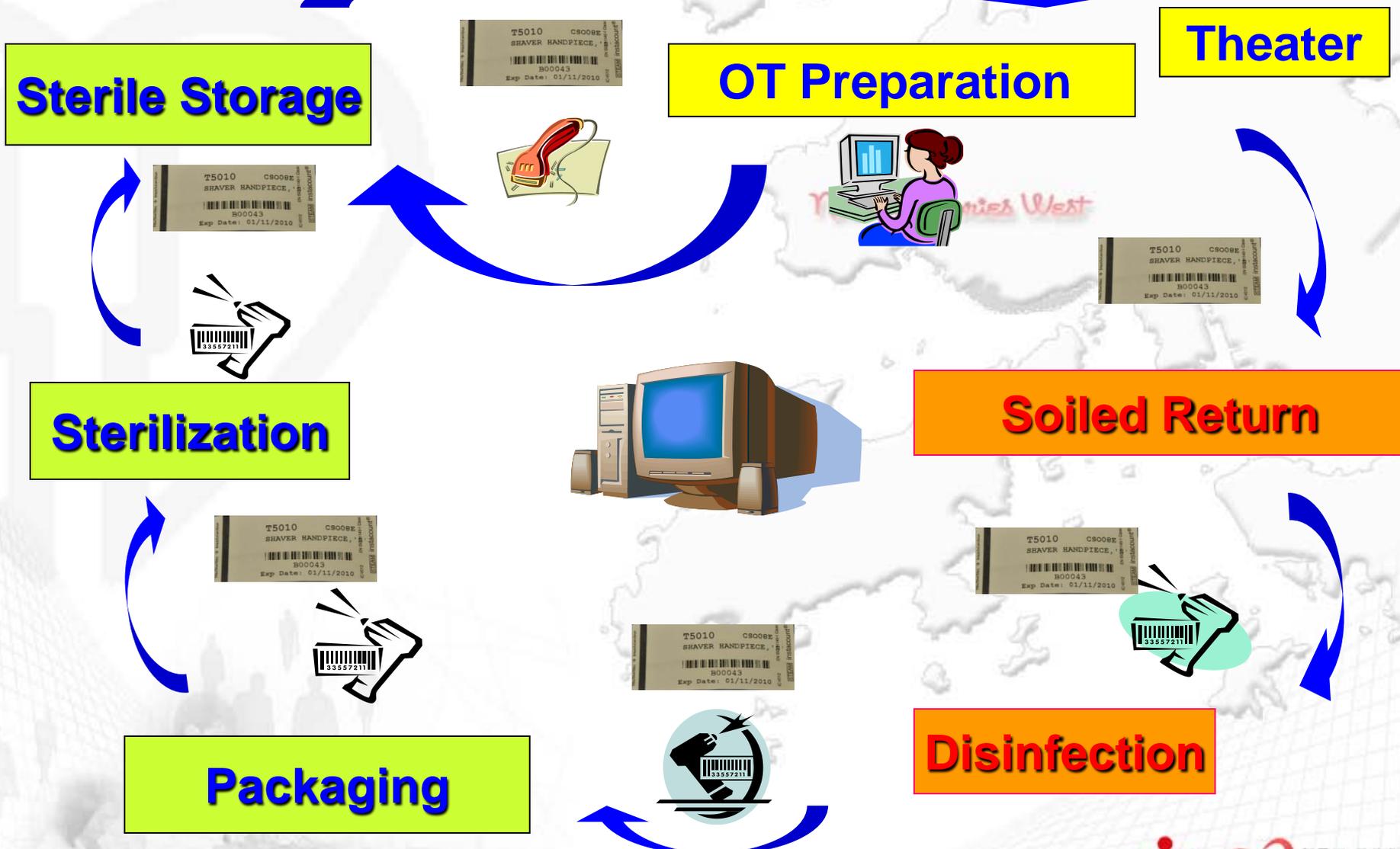
Scan the barcode Label if qty. is required auto-refill



Electronic Tracking in NTWC



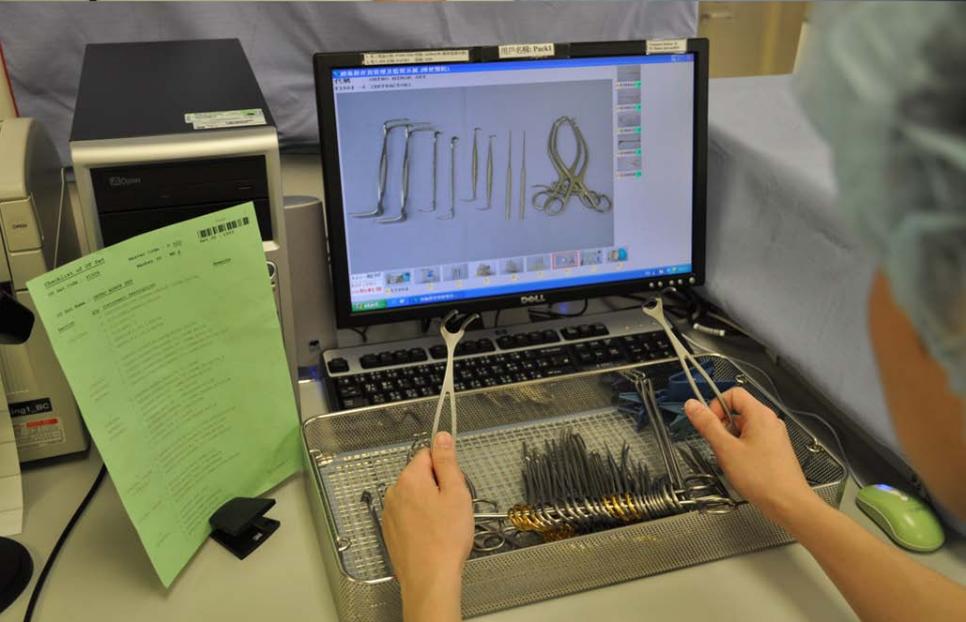
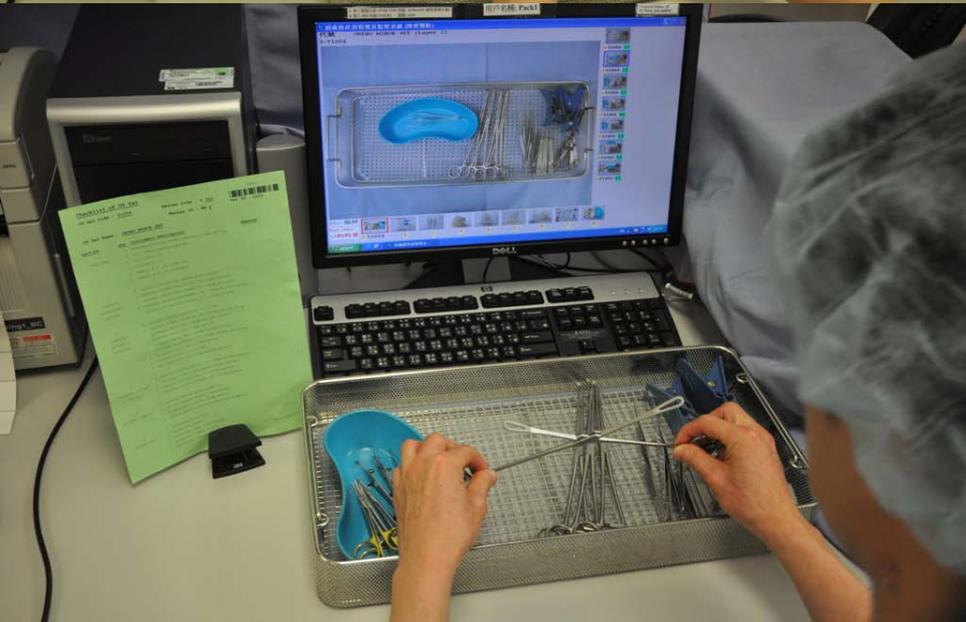
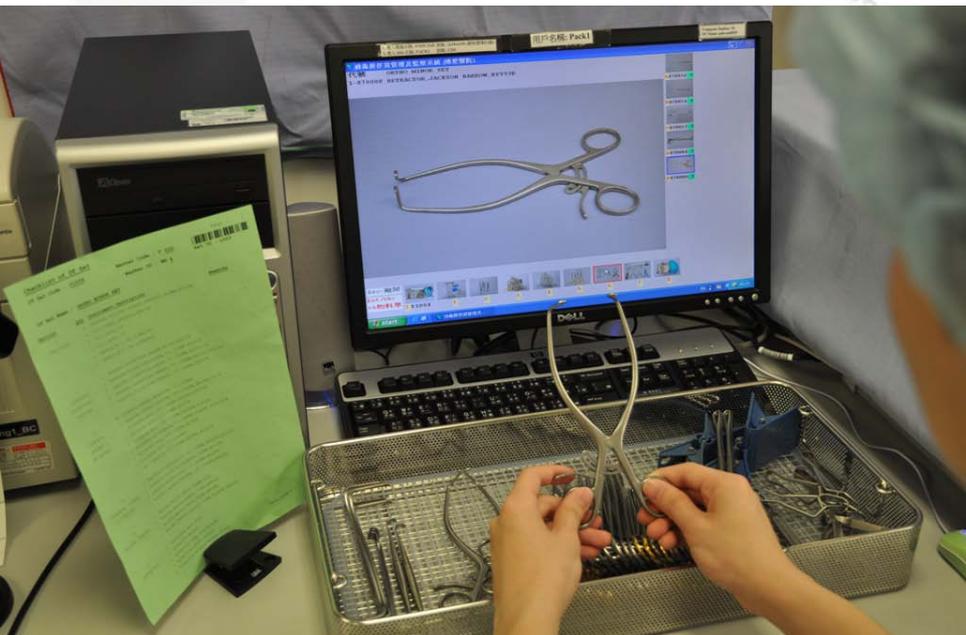
Tracking and Tracing throughout Decontamination cycle



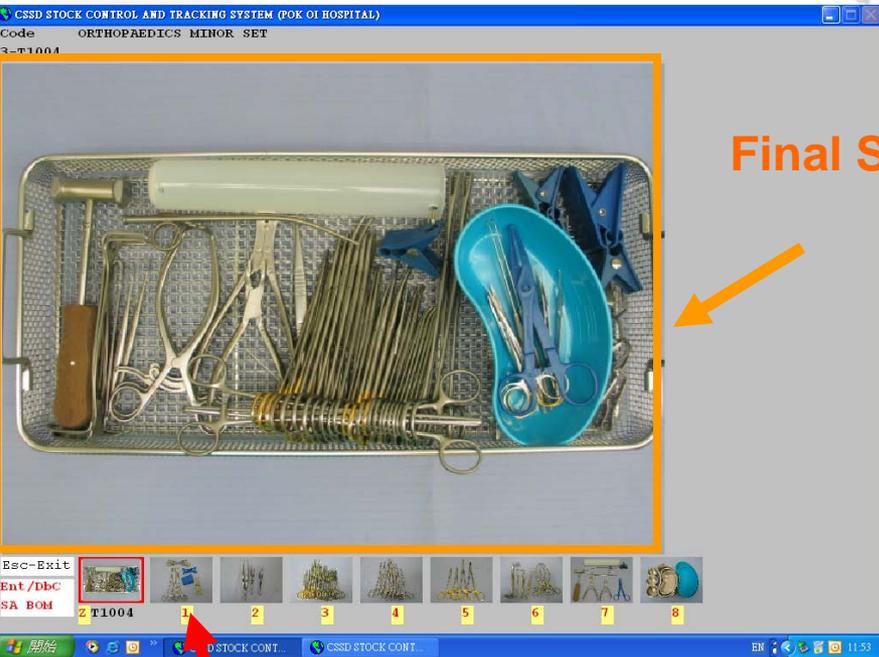
Tracking decontamination cycle



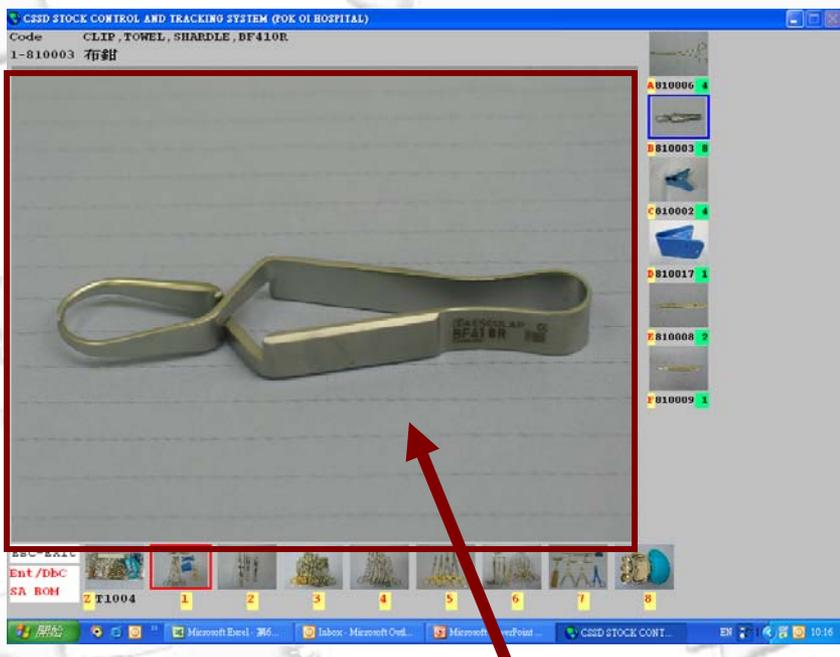
Image for Surgical Instrument Set



Three level of Image



Final Stage



Individual instrument



8 Groups of Instrument

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(9) Way Forward

Way forward

- Establish governance structure
- Enhance corporate guidelines
- Develop corporate tracking system
- Eliminate flash sterilization
- Centralization of decontamination centres
- Clear demarcation to segregate dirty and clean
- Fade out linen wrapper
- Foster training and development
- Enhance engineering support

Way forward ?????

- Pharmacist
- Engineer
- Nurse
- Administrator

Who is the manager?

- Denursing in CSSD
- Sick pool
- Career development



Way forward ?????

- Water Quality – use of Reverse Osmosis water
- Air Quality - Inspection/Assembly/Packing (IAP) room
 - ISO 14644 Class 8 clean room standard
 - Double locking door for IAP room
- Steam Quality – clean steam
- The degree of Centralization
 - Cluster base
 - Hospital base

Way forward ?????

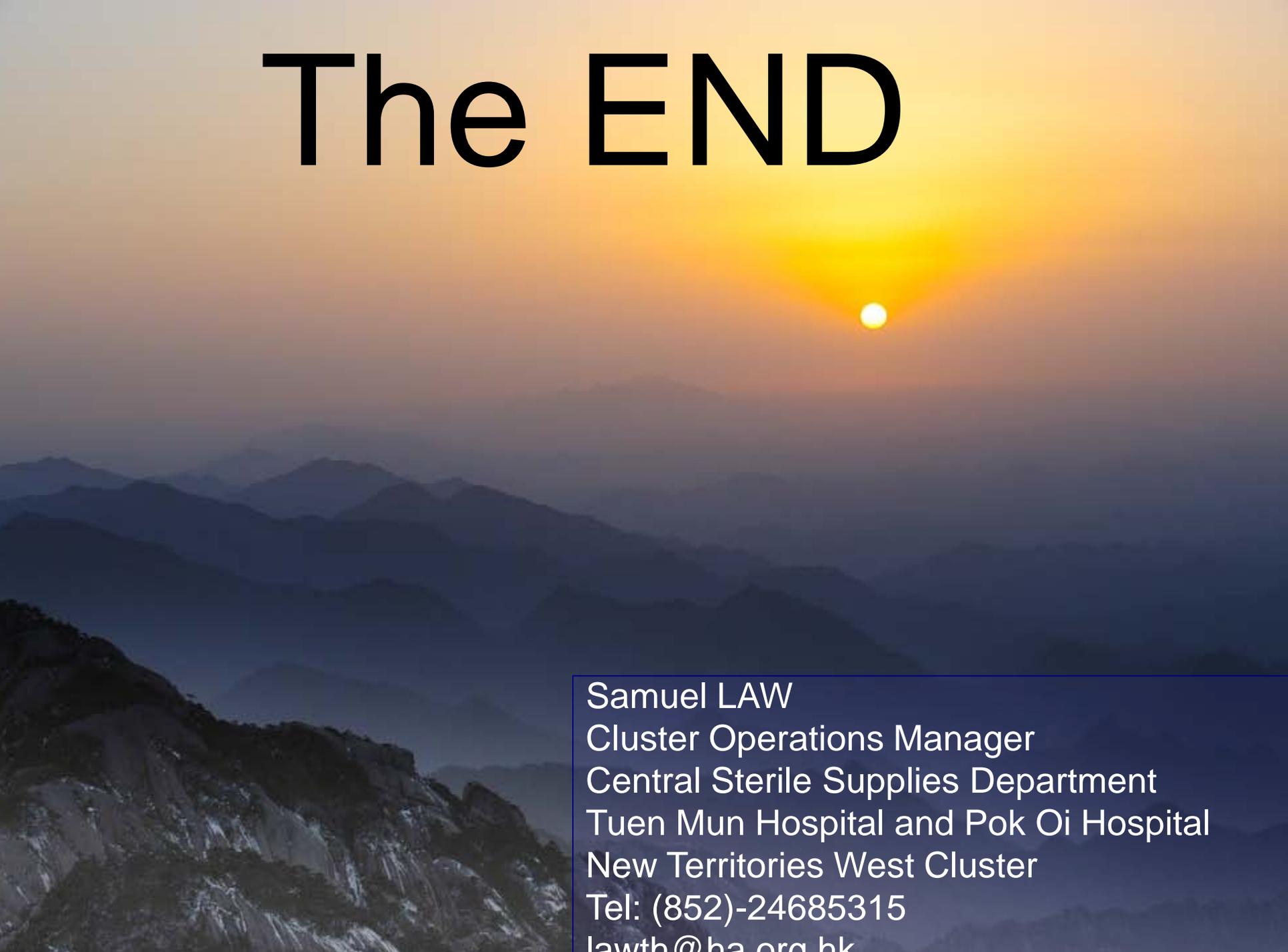
- Is it the best practice to extensively use of container system?
- Shall we fade out all linen items?
- Can outsourcing solve the existing problem?
- How to sustain training and development of staff competence?
- Adoption of standard – ISO, EU norm, HTM, AAMI, AS, WS (Chinese standard) etc

Way forward ?????

- High volume high turnover (↑ demand)
- What is the best practice?
 - decontamination of endoscope at the point of use
 - Storage of disinfected endoscope
 - Transportation of disinfected endoscope



The END

A sunset over a mountain range. The sun is a bright yellow circle in the upper right, with a gradient of orange and yellow in the sky. The mountains are layered in shades of blue and grey, receding into the distance. The foreground shows a rocky, dark mountain slope.

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