Sterilization Service Revolution in Hospital Authority Hospital

Date: 2nd March 2017
Workshop on Sterilization and Infection Control related to Operating Theatre
Lecture Theatre, G/F, Centre for Health Protection, 147C Argyle Street, Kowloon

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Content

A. Introduction of Central Sterile Supplies Department

B. Hong Kong Experience of Hospital Accreditation

C. Sterilization Service Revolution in Tuen Mun Hospital

D. Quality Management System for Reprocessing Reusable Medical Devices in Hospital

E. Improvement in Corporate Level

A. Introduction of Central Sterile Supplies Department

Tuen Mun Hospital

Pok Oi Hospital

Tin Shui Wai Hospital

Vision:

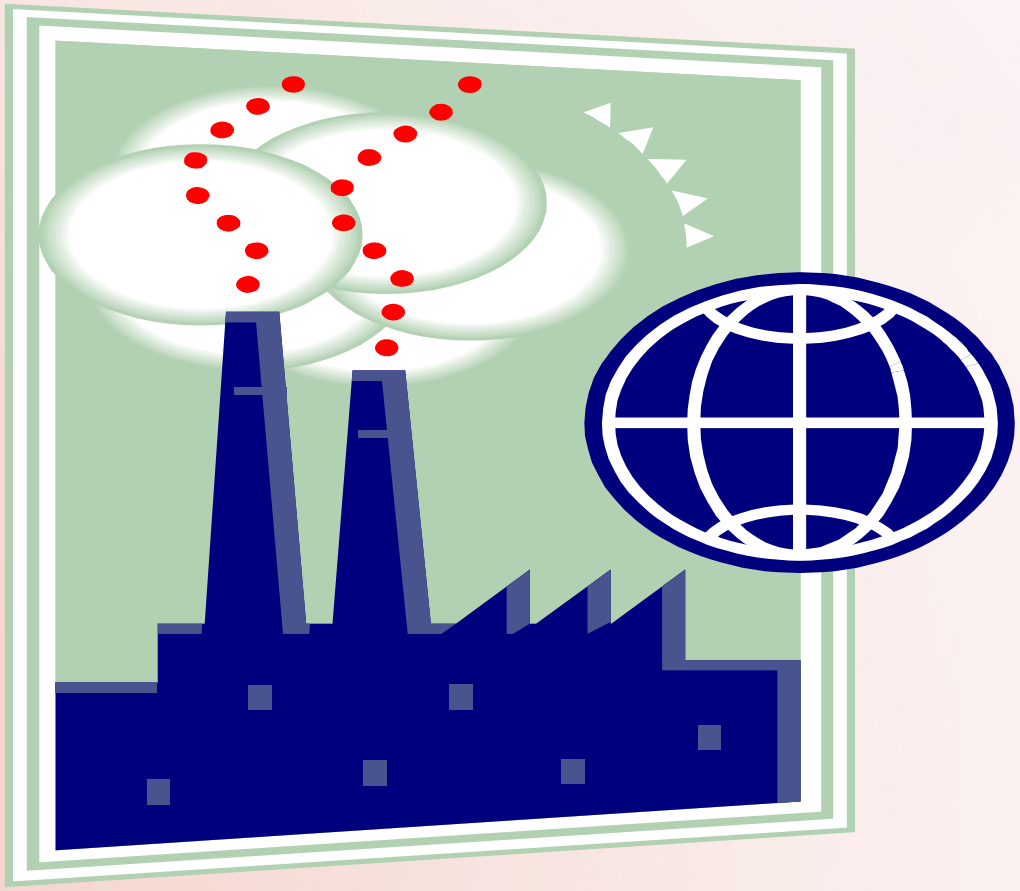
Be a professional disinfection and sterilization service provider

Mission:

To provide quality disinfection and sterilization service for reusable medical device

Role of Reprocessing Center

Reprocessing Center – A Factory in Hospital



Traditional CSSD

Reprocessing of Linen Items

Traditional CSSD

Reprocessing of Reusable Medical Device and Ward Procedure Set

Scope of Services of Traditional CSSD

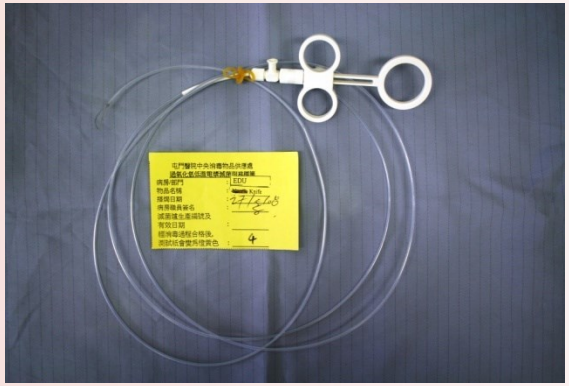
1. Sterile Dressing Packets
2. Sterile Ward Procedure Sets
3. Sterile Theatre Linen Packs
4. Sterile Instrument Packets
5. To reprocess user-owned reusable medical devices

Scope of Services of Traditional CSSD

6. To provide central disinfection services of medical equipment and device



7. To monitor, control and reprocess reuse Single Use Medical Device

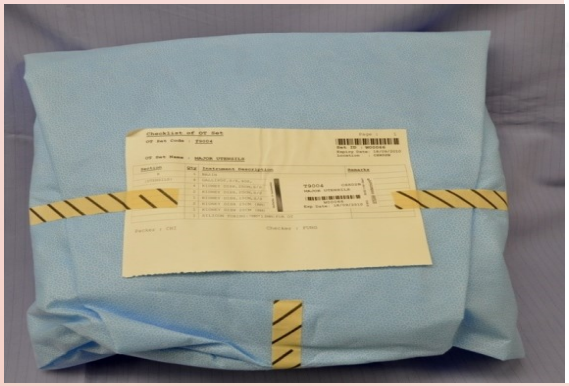



A. Introduction of Central Sterile Supplies Department



Theatre Sterile Supply Unit

TSSU

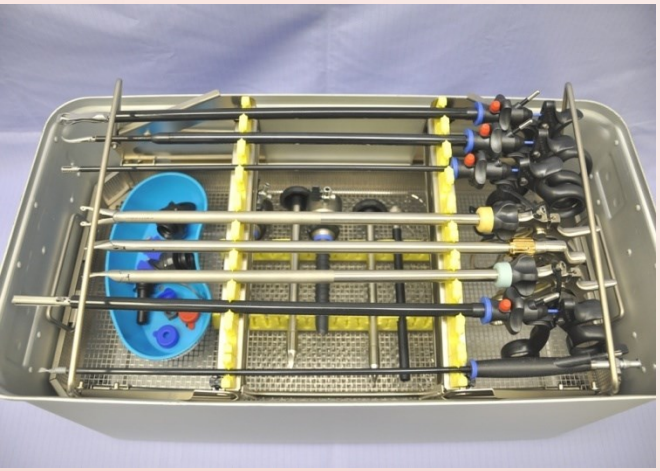


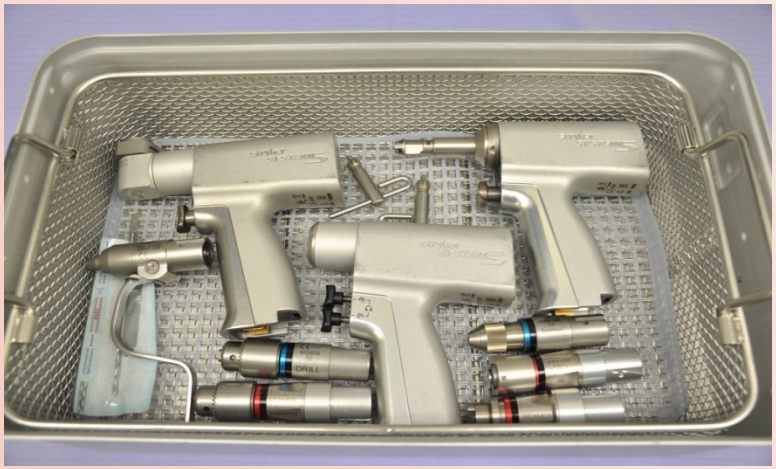
Scope of Services of TSSU

To reprocess operating theatre surgical instruments

Scope of Services of TSSU

To reprocess operating theatre surgical instruments





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B. Hong Kong Experience of Hospital Accreditation

The Australian Council on Healthcare Standards (ACHS) conducted accreditation pilot exercise for 5 public hospitals in Hong Kong in 2009

5 Public Hospitals:

- Caritas Medical Centre
- Pamela Youde Nethersole Eastern Hospital
- Queen Elizabeth Hospital
- Queen Mary Hospital
- Tuen Mun Hospital

3 Private Hospitals:

- Baptist Hospital
- Hong Kong Sanatorium & Hospital
- Union Hospital

C. Sterilization Service Revolution in Tuen Mun Hospital

ACHS Surveyors recommended Key Address Areas in Sterilization Service of Surgical Instrument

1. Lack of clear demarcation of dirty and clean zones in Operating Theatre for instrument reprocessing

2. Elimination of flash sterilization for surgical instrument

3. Lack of effective tracking and tracing of surgical operation instruments

4. Deficit in Governance Structure

Sterilization Service Revolution in TMH

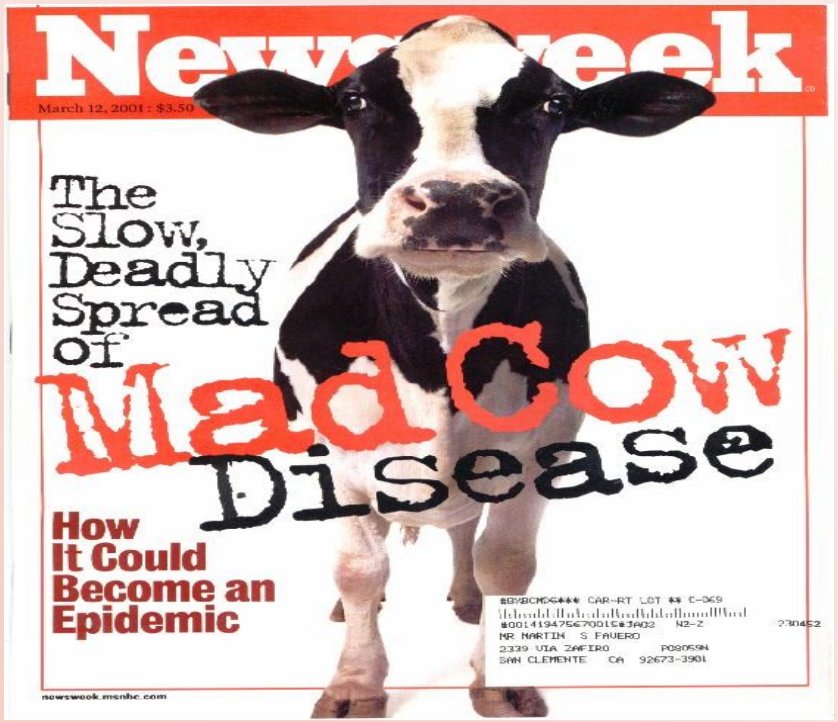
Tuen Mun Hospital also encountered the same issues

1.Dirty and Clean

2.Flash Sterilization

Sterilization Service Revolution in TMH

3.Lack of effective tracking and tracing of surgical operation instruments



A tracking system should be in place that permits recall of devices used on high-risk tissue and high-risk patients. This tracking system should permit identification of the patient on which the devices were used, the date they were used, the procedure performed, and the surgeon's name.

ANSI/AAMI ST79:2010

Background of TMH

Limitation of Sterilization Facilities in 2010

- Four Satellite Reprocessing Centres in OT
- Flash sterilization method as routine practice
- No formal Theatre Sterile Service Unit in TMH
- Insufficient surgical instrument inventory
- Insufficient manpower for instrument reprocessing
- Insufficient space for storage and reprocessing instrument
- Insufficient decontamination equipment
- Surgical instrument user (OT staff) had to shoulder the role of sterile service provider

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We need to change !!!

CSSD of Tuen Mun Hospital initiated a pilot project and act as a model for sterilization service enhancement

Pilot Project on Sterilization Enhancement in TMH CSSD

First HA CSSD to renovate between March 2011 and June 2012

Sterilization Enhancement Project in Tuen Mun Hospital

Aim :

- Conversion of old Central Sterile Supplies Department (CSSD) to a be **Central Decontamination Center** in TMH
- Modernize TMH CSSD to **merge CSSD and Theatre Sterile Supplies Unit (TSSU) functions** together within one department
- Upgrade the quality management system in CSSD to meet with international standard of decontamination practice

New Design of CSSD (Mar 2011- Jul 2012)

The Hardware Requirement

① Infrastructure Requirement

② Decontamination Equipment Requirement

Design and Management of new CSSD

Quality Systems
Medical Devices:
EN ISO 13485:2003

Reference to HA Guidelines on Disinfection & Sterilization of Reusable Medical Devices for OT

Quality Manual
Policies and procedures

Decontamination Equipment

Washer Disinfector:
ISO 15883
Steam Sterilizer :
EN 285
Ultrasonic Cleaner :
AS 2773

The Facility

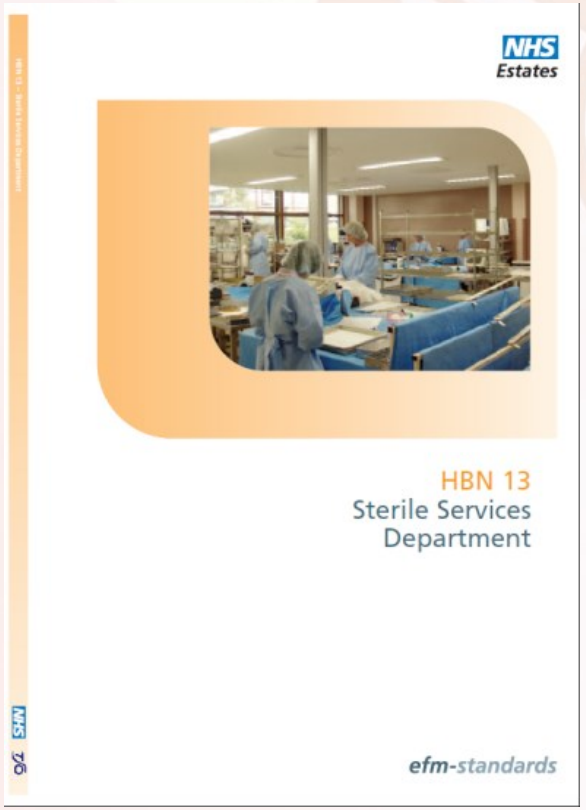
Environment Design:
Hospital Building Note 13 (UK)
Environment Control
ISO 14644

Management

- **Training**
- **Resources Monitoring**
- **Auditing**
- **Customer Focus**
- **Product Realization**
- **Measure, Analysis and Improvement**
- **Tracking & Tracing of Instruments**

① Infrastructure Requirement

- Hospital Building note 13
- Demarcation of Dirty and Clean in Decontamination area
- ISO 14644 Class 8 Clean room Standard in Inspection Assembly Packing room
- Ventilation and air flow
- Temperature and humidity requirement
- Adequate lighting
- Air exchange rate



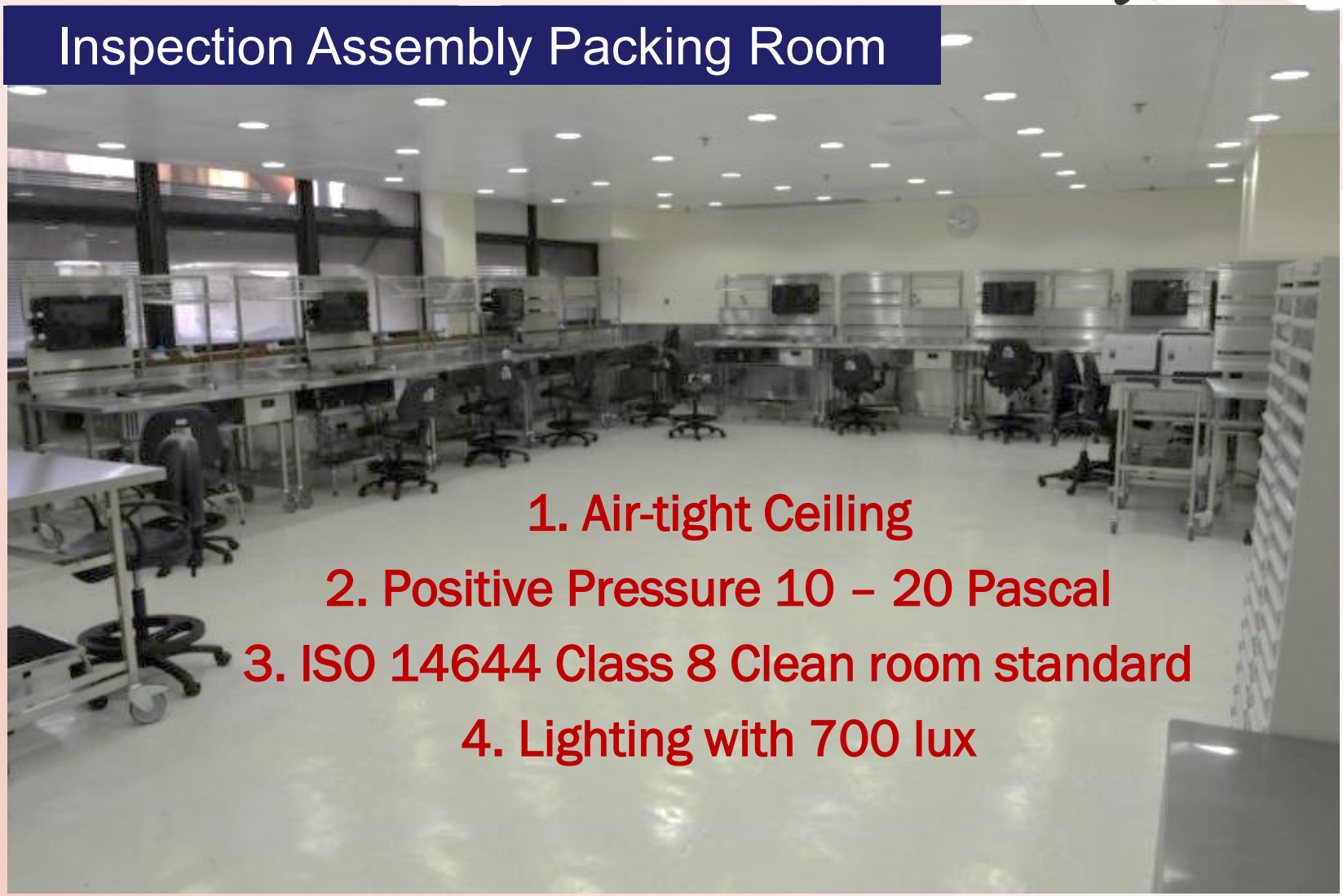
① Infrastructure Requirement

Demarcation of Clean and Dirty Area

① Infrastructure Requirement

Demarcation of Clean and Dirty Area

Inspection Assembly Packing Room

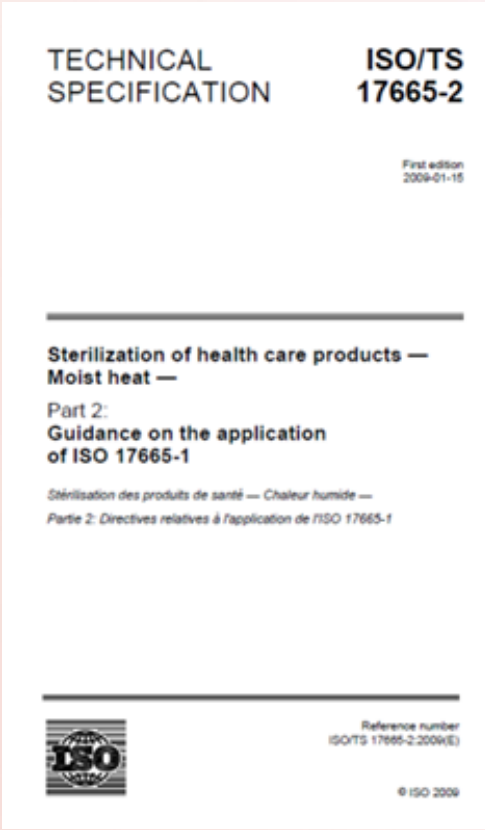


② Equipment Requirement

Standards for Reference

Standards of Steam Sterilizer

ISO 17665 & EN 285



TECHNICAL SPECIFICATION

ISO/TS 17665-2

First edition
2009-01-15

Sterilization of health care products — Moist heat —

Part 2:
Guidance on the application of ISO 17665-1

Stérilisation des produits de santé — Chaleur humide —
Partie 2: Directives relatives à l'application de l'ISO 17665-1

Reference number
ISO/TS 17665-2:2009(E)

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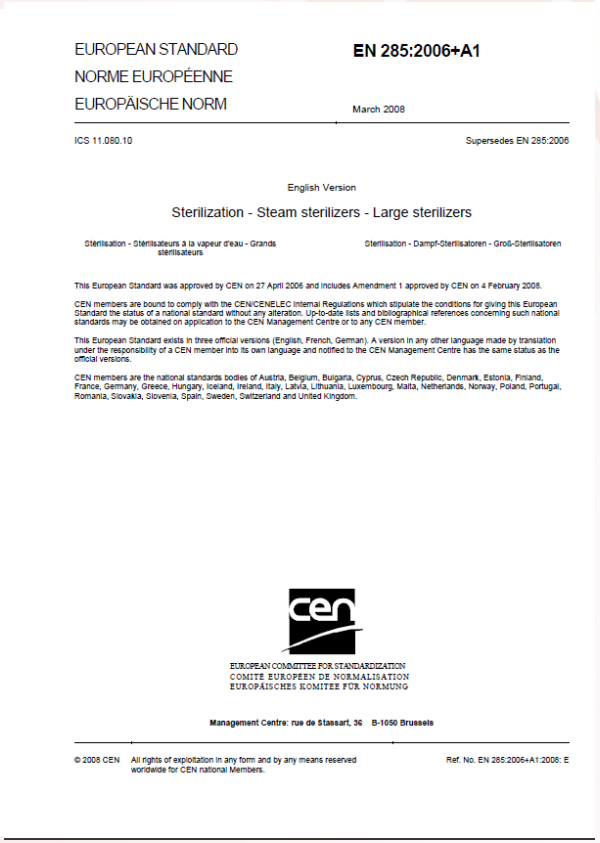

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 285:2006+A1

March 2008

ICS 11.080.10

Supersedes EN 285:2006

English Version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 27 April 2006 and includes Amendment 1 approved by CEN on 4 February 2008.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

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Ref. No. EN 285:2006+A1:2008: E

② Equipment Requirement

Standards for Reference

Standard of Hydrogen Peroxide Sterilizer

STERRAD 100NX

STERRAD 100S

INTERNATIONAL STANDARD

ISO 14937

Second edition 2009-10-15

Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

Stérilisation des produits de santé — Exigences générales pour la caractérisation d'un agent stérilisant et pour la mise au point, la validation et la vérification de routine d'un processus de stérilisation pour dispositifs médicaux

Reference number ISO 14937:2009(E)

© ISO 2009

ISO 14937

② Equipment Requirement

Standards for Reference

Standards of Washer Disinfector

INTERNATIONAL STANDARD **ISO 15883-6**

First edition
2011-04-15

Washer-disinfectors —

Part 6:
Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

Laveurs désinfecteurs —

Partie 6: Exigences et essais pour les laveurs désinfecteurs utilisant une désinfection thermique pour les dispositifs médicaux non invasifs, non critiques et pour l'équipement de soins de santé

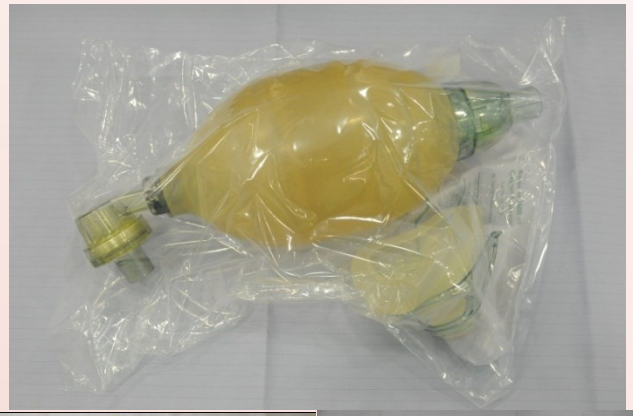
Reference number
ISO 15883-6:2011(E)

© ISO 2011

EN ISO 15883

Ultrasonic Cleaner
AS 2773

New Scopes of Service



1. Thermal Disinfection

Thermal disinfection was used to replace chemical disinfectant so as to ensure staff and patient safety

New Scopes of Service

2.Fade Out Linen Item

Use disposable drapes

New Scopes of Service

3. Fade Out Production Dressing Item

Use pre-sterile ones available in the market

→Handover delivery role of sterile proprietary consumables to Central Procurement Material Management Unit

New Scopes of Service

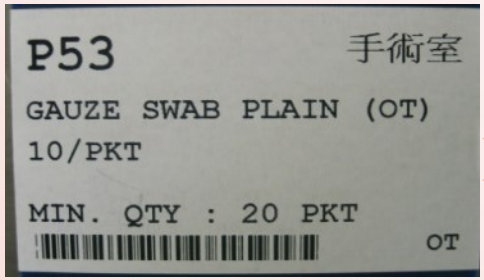
4. Reprocessing of Reusable Polypropylene Hollowares by Disposable One

- Shifting the supply of disposable hollowware to Central Distribution Centre(CDC) →Release production capacity and focus on clinical service provision

New Scopes of Service

5. Topping Up (Auto-Refill System)

Bar Code Scanner



Bar Code label

Check Quantity

Synchronize the data of portable scanner to computer

Generate a report and prepare refill items

New Scopes of Service

6. Focus on Surgical Implant and Instrument

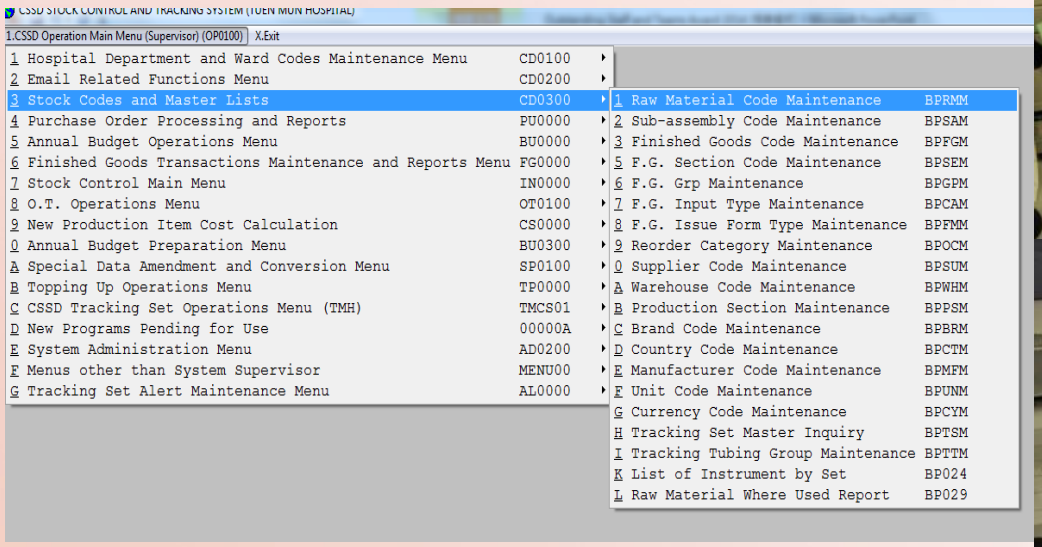
1. To reprocess surgical instruments

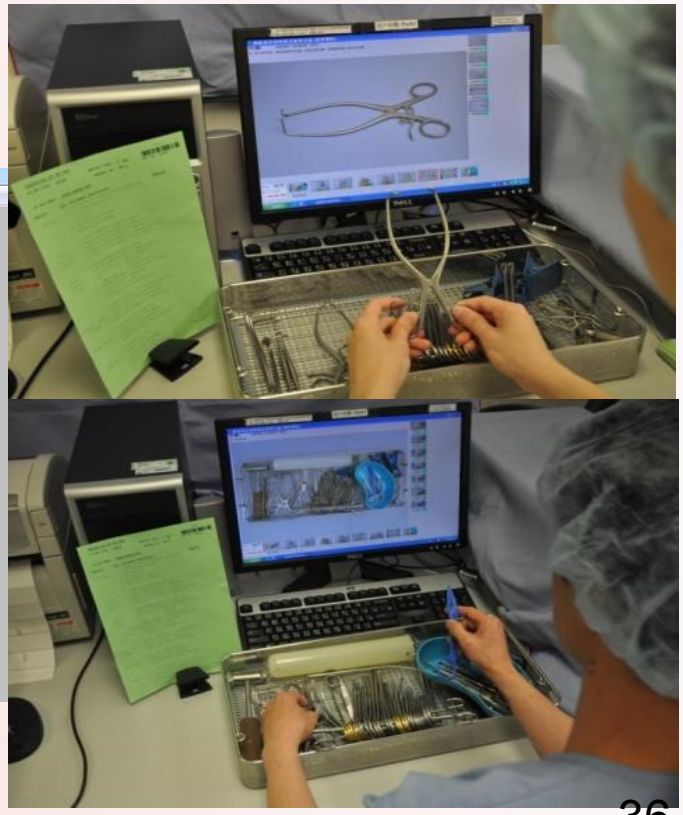
2. Elimination of Flash Sterilization

Development of Tracking System

The Other Function of Tracking System

- Tracking and Tracing System for Surgical Instrument
- Procurement and Materials Management
- Annual Budgeting and Forecasting
- Stock Distribution for Clinical Users
- Internal marketing (cross charging)



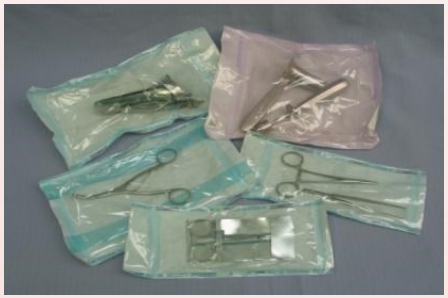


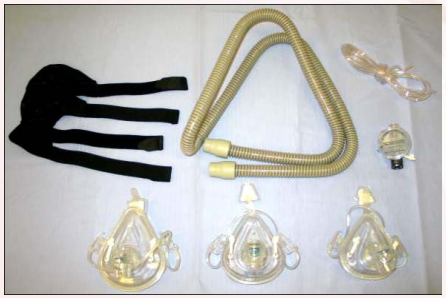
Role of Reprocessing Center

Centralization

Heart of Hospital in terms of Infection Control

C. Sterilization Service Revolution in Tuen Mun Hospital

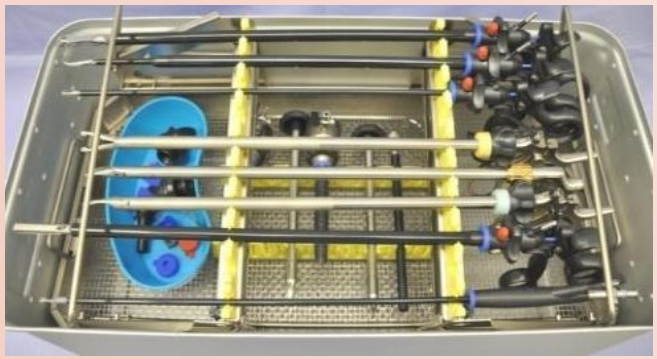


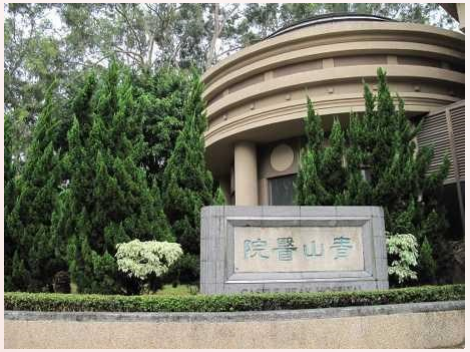


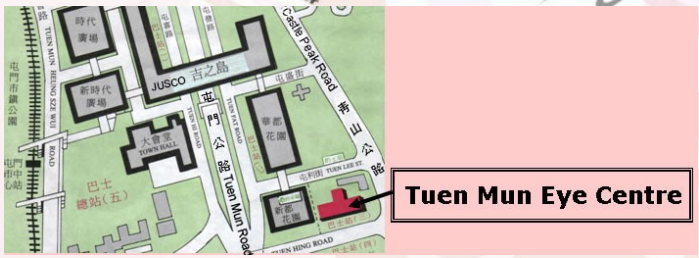

TSSU

Centralization within a hospital

CSSD





Centralization of Sterile Supply Services within NTWC

Content

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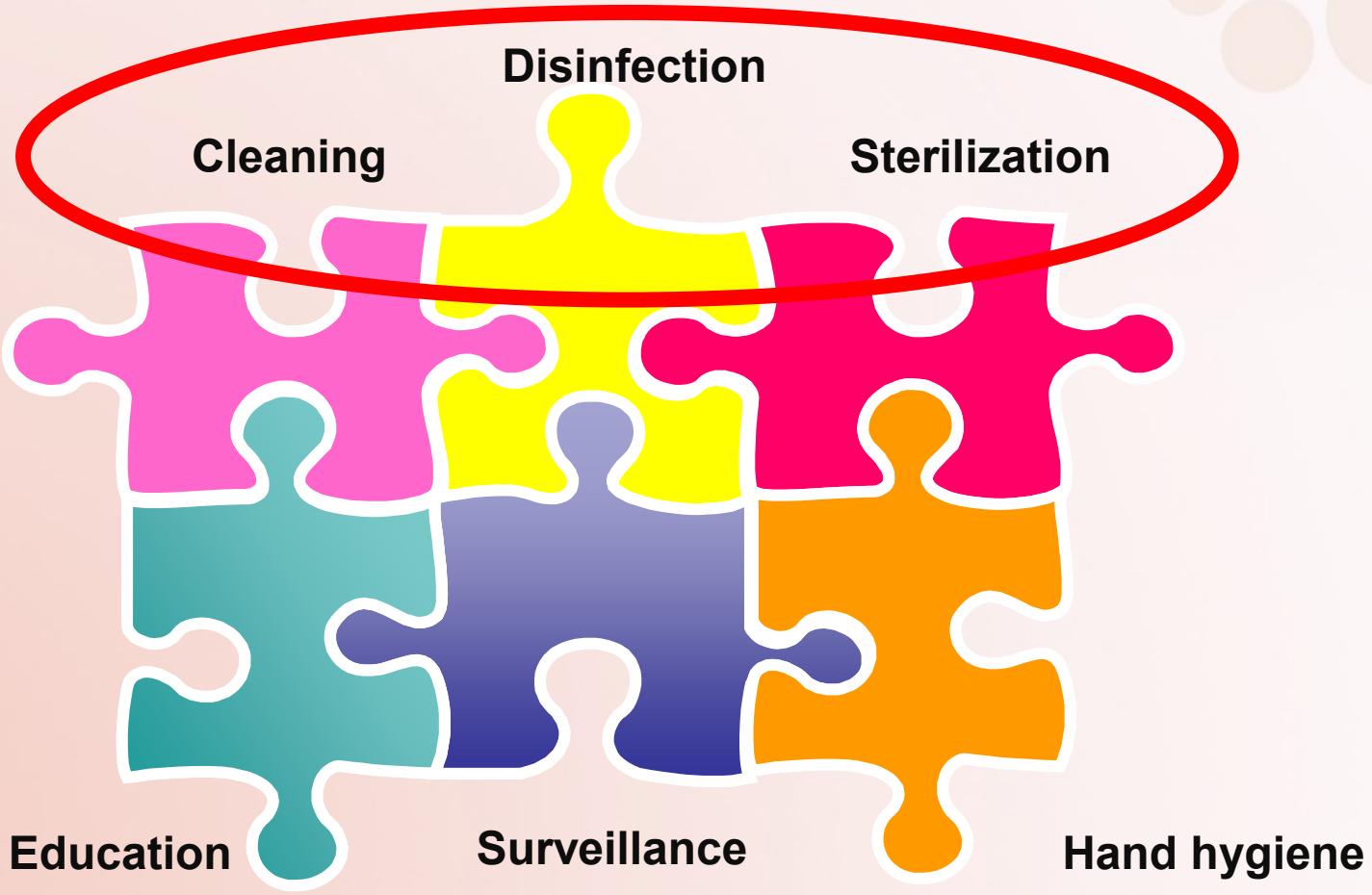
Infection Control in Hospitals

Importance of Decontamination Practices in Infection Control



Risks of Inadequate Decontamination Reprocessing Practices

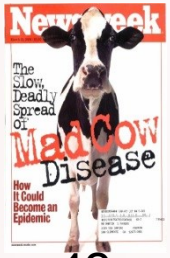
1) Affect the efficacy of the disinfection or sterilization process

2) Transfer of foreign protein which may cause adverse reaction. It poses the risk of spreading TSE's (CJD / vCJD)

3) Transfer of micro-organisms which may cause infection

4) Transfer of particulate materials which may cause granuloma or adhesions in wounds

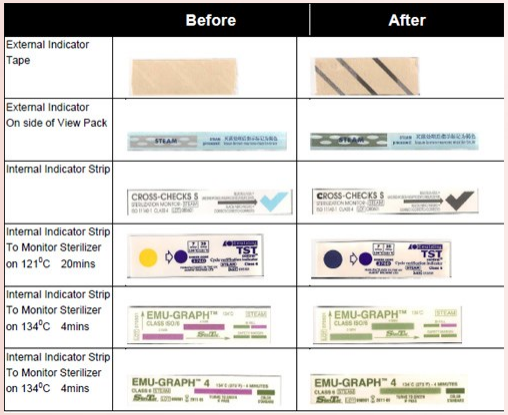
5) Transfer of bacterial endotoxins which may cause fever



How do we assure 'Sterility'?

What is sterility?

1. Can we base on the sterilizer printout to assure sterility?
2. Can we trust the chemical indicator label?
3. Can we trust the Biological Indicator ?
4. Is it a routine practice for laboratory test on sterility?



Process Control

D. Quality Management System for Reprocessing Reusable Medical Devices in Hospital

How to maintain and improve the quality continuously?

CSSD needs a Quality Management System

Quality Management System - ISO 13485

Composed of 8 sections:

1. Scope of standard
2. References
3. Terms & definitions contained in standard
4. Quality management system
5. Management responsibilities
6. Resource management
7. Product realisation
8. Measurement, analysis and improvement

CSSD Quality Management System

Content

1. Introduction and Department Profile

2.Quality Policy and Objective

3. Management Responsibility

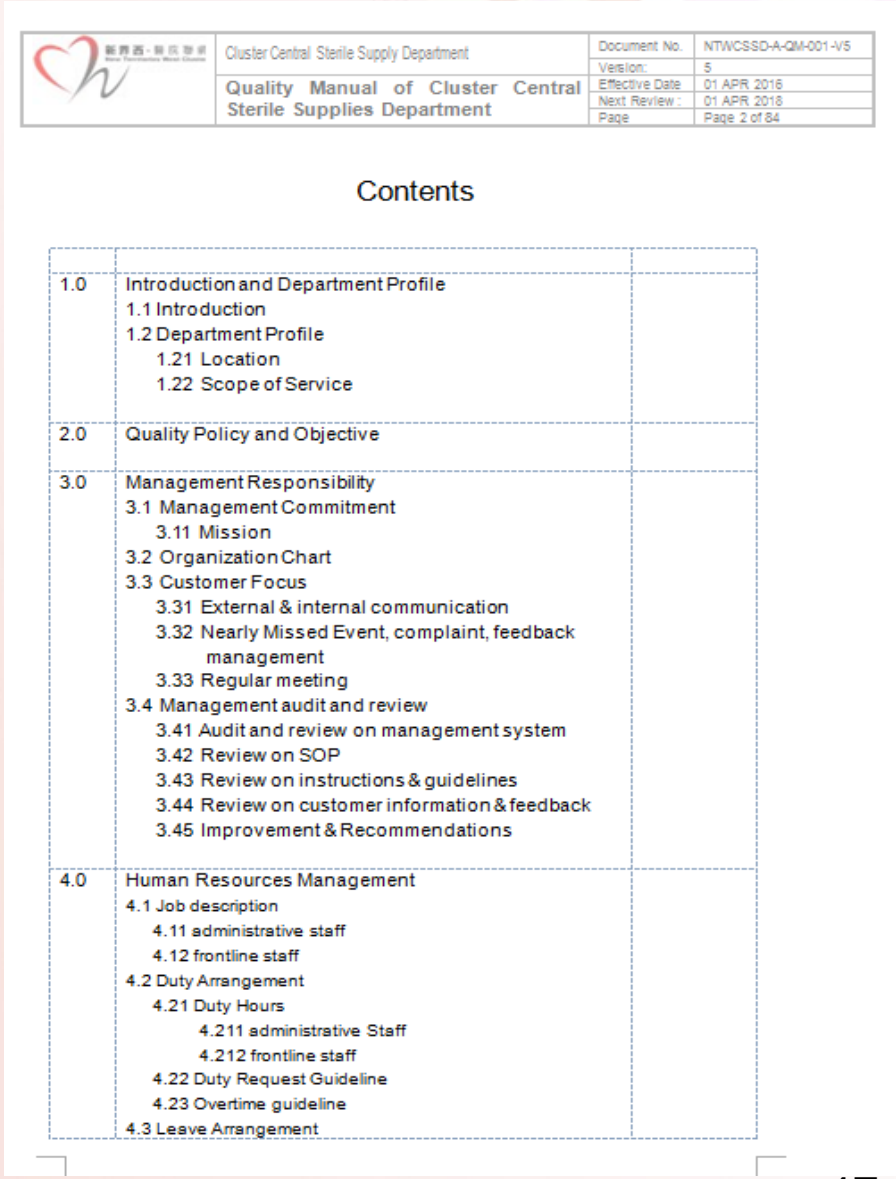
4.Human Resources Management

5.Material Management System

6.Production Standard

7.Risk Management, Measurement, Analysis and Continuous Quality Improvement

8.Control of Document



Cluster Central Sterile Supply Department	Document No.	NTWCSSD-A-QM-001-V5
	Version:	5
Quality Manual of Cluster Central Sterile Supplies Department	Effective Date	01 APR 2016
	Next Review :	01 APR 2018
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Contents

Credential – Qualification of Staffs

Range of Duties	WMII/ GSA	WMI/ TSA	Artisan/ TSA	SSS & RN	NO	COM
Infection Control	✓	✓	✓	✓	✓	✓
Fire Safety	✓	✓	✓	✓	✓	✓
Manual Handling	✓	✓	✓	✓	✓	✓
Occupation Safety & Health	✓	✓	✓	✓	✓	✓
Hygiene procedure	✓	✓	✓	✓	✓	✓
Understanding of quality systems	✓	✓	✓	✓	✓	✓
Basic Concept of Tracking and Traceability	✓	✓	✓	✓	✓	✓
Collect and handle soil instrument set	✓	✓	✓	✓	✓	✓
Recognize Instrument Set	✓	✓	✓	✓	✓	✓
Assemble Instrument Set, Linen Pack and Dressing Pack	X	✓	✓	✓	✓	✓
Assemble High Level Disinfection Item	X	✓	✓	✓	✓	✓
Operate Sterilizer	X	X	✓	✓	✓	✓
Basic Stock Control	X	X	✓	✓	✓	✓
Basic IT skills	X	X	✓	✓	✓	✓
Tracking System	X	X	✓	✓	✓	✓
Advanced IT skills	X	X	X	✓	✓	✓
Environmental Monitoring	X	X	X	✓	✓	✓
Quality Sampling	X	X	X	✓	✓	✓
Supervise Staff	X	X	X	✓	✓	✓
Monitor Stock level	X	X	X	✓	✓	✓
Handle Customer Complaint	X	X	X	✓	✓	✓
Internal Auditing	X	X	X	✓	✓	✓
Train staff in special duties	X	X	X	✓	✓	✓
Procurement	X	X	X	X	✓	✓
Recruitment / Interview	X	X	X	X	✓	✓
Resources Management	X	X	X	X	X	✓
Liaison Duties	X	X	X	X	X	✓

Quality Management System-Training

To develop and implement in-house training module with 3 phases for new join staff.

Module I. NTWC CSSD Training Schedule of PCAII

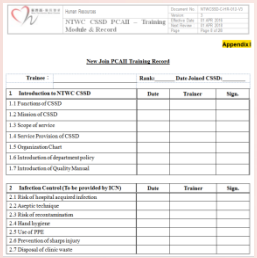
It covers comprehensive introduction of basic working knowledge.

Module II. Mentorship Scheme of New Join PCAII (8-weeks)

All new PCAII would be assigned with an experienced PCAII as mentor to coach for 8 weeks.

Module III. NTWC Tier 1 In-house CSSD Training course

- It is a training course delivered by supervisors and management to summarize the working knowledge and skills.
- **Multiple choice questions** are designed for **assessment** and **evaluation of training program**



NTWC CSSD PCAII – Training Module & Record

Appendix I

New Join PCAII Training Record

Trainee : Rank: Date Joined CSSD:

1 Introduction to NTWC CSSD	Date	Trainer	Sign.
1.1 Functions of CSSD			
1.2 Mission of CSSD			
1.3 Scope of service			
1.4 Service Provision of CSSD			
1.5 Organization Chart			
1.6 Introduction of department policy			
1.7 Introduction of Quality Manual			

2 Infection Control (To be provided by ICN)	Date	Trainer	Sign.
2.1 Risk of hospital acquired infection			
2.2 Aseptic technique			
2.3 Risk of recontamination			
2.4 Hand hygiene			
2.5 Use of PPE			
2.6 Prevention of sharps injury			
2.7 Disposal of clinic waste			

Quality Management System-Training

Training for Senior Staff / Supervisor

NTWC CSSD Tier-2 in-house training course for Supervisor

Content:

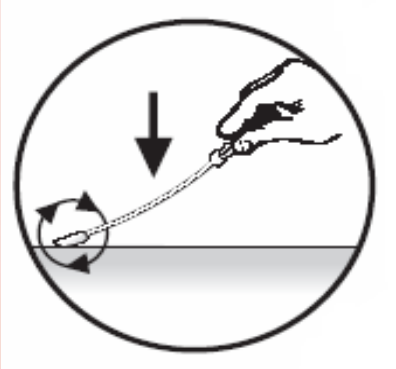
- Theories on Decontamination Sciences
- Operational Management and quality management of CSSD
- Management Principle and supervisory skills

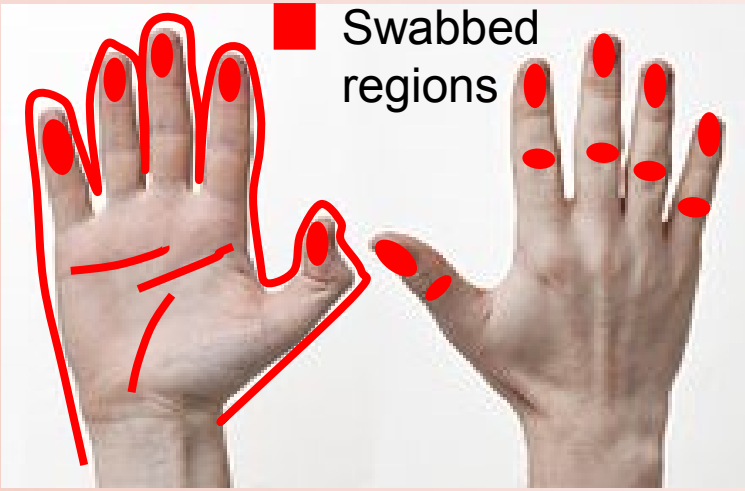
Evaluation of hand washing efficiency

- A Pass / Fail limit of 600 RLU was set following the initial wash.
- If the levels were > 600 RLU, operators were told to re-wash their hands and were re-tested.
- If the ATP levels were stills > 600 RLU, the operators were re-trained on their hand washing technique.

Hand Hygiene Monitoring by ATP Swab Test

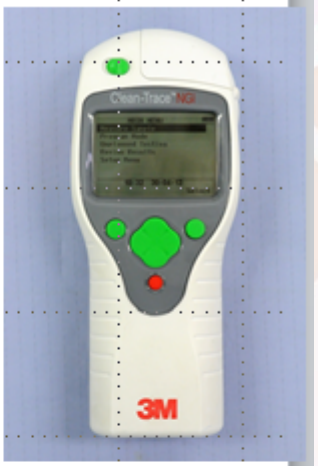
Swab → **Reaction – Click & Shake** → **Measure & Record**





Hand Hygiene Monitoring by ATP Swab Test

	Surprise check (Pre-wash)	Immediately retest (Pro-wash)
% staff surveyed (29)	85% = 29 (surveyed staff) / 34 (packing staff)	
Relative Light Unit (RLU) detected on staff strong hand (慣用手)		
Range (29)	404 - 30332	86 - 3643
Max (29)	30332	3643
Min (29)	404	86
Median (29)	2844	410
	Average RLU	
All staff (29)	5351	755
Female (25)	4953	548
Male (4)	6343	1594
Entry before 2003 (10)	3019	338
Entry after 2003 (19)	6365	967
a. Entry between 2003 – 2011 (>1 ICN course attended) (7)	6365	420
b. Entry less than 18 months (very new staff =1 ICN course attended) (12)	6785	1376



Target group

Compliance of CORRECT washing hand technique.

5.5 Environmental Control

Table 1 Environment, ventilation, and lighting Requirements

Rooms	Classification	Environment specification		Ventilation		Lighting	
		Temperature range °C	Relative humidity %	Minimun total air change per hour*	+/- with respect to (wrt)	Lux	Position
Wash room / decontamination area	Dirty	18-22	30-60	10	Not +ve wrt surrounding areas	500 300	Bench Floor
IAP room / Packing area	Clean	18-22	40-60	10	+ve wrt all area	700 500	Bench Floor
Sterilizer loading area / sterilization area	Clean	18-22	30-60	10	+ve wrt all other area -ve wrt IAP	300	Bench
Processed products store / Sterile store	Clean	18-22	30-60	4	-ve wrt cooling +ve wrt despatch	300	floor

*Ventilation requirement, minimum total air change per hour recommended by Association for the Advanced of Medical Instrumentation (AAMI).

5.5 Environmental Control

ISO 14644 Class 8
Clean room standard

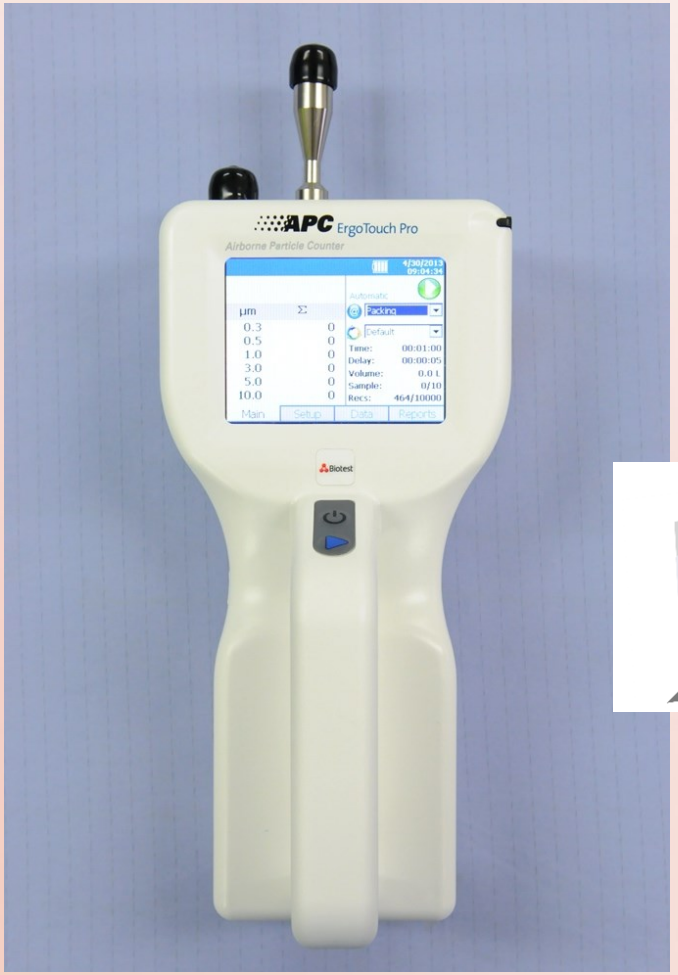
Table 1 — Selected airborne particulate cleanliness classes for cleanrooms and clean zones

ISO classification number (*N*)	Maximum concentration limits (particles/m^3 of air) for particles equal to and larger than the considered sizes shown below [concentration limits are calculated in accordance with equation (1) in 3.2]					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

NOTE Uncertainties related to the measurement process require that concentration data with no more than three significant figures be used in determining the classification level

5.5 Environmental Control

Particle Count Monitoring of an IAP room



Floor plan of 15 packing locations (217m2)

	E機尾		A機尾	
	1	2	3	
	4	5	6	喉房
爐位:門	7	8	9	潔具房
	10	11	12	
	13	14	15	抽風櫃

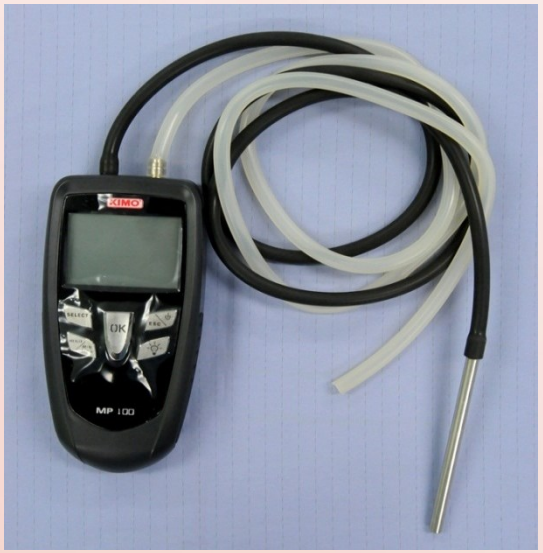
PASS

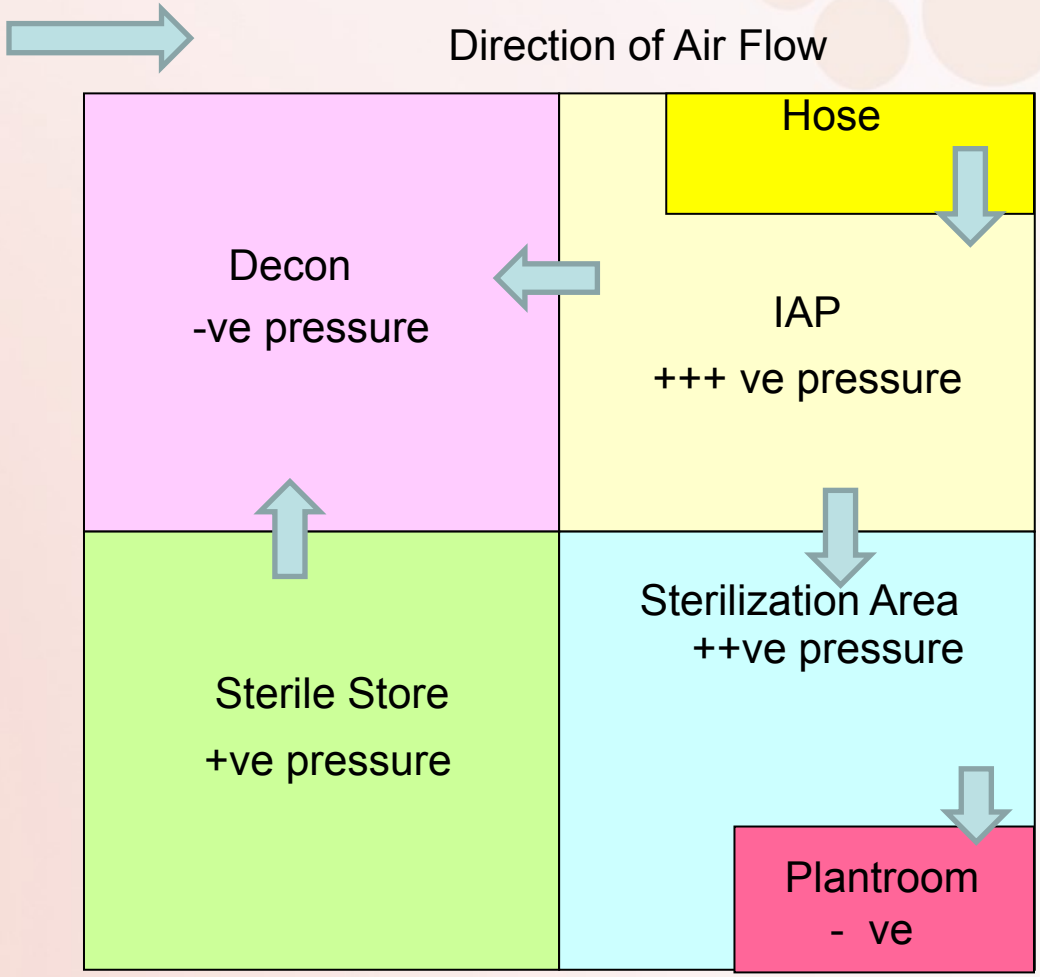
	Particle Size (um)					
	0.3	0.5	1.0	3.0	5.0	10.0
	Concentration (Particle count / m3 of air)					
Average	504	101	24	4	2	1
Max	1196	296	63	6	4	1

5.5 Environmental Control

Pressure Difference Monitoring of an IAP room

Minimum pressure difference:
10-20Pa across adjacent
compartment of IAP room.





Quality Management System

Validation and Routine Control

Washer Disinfector as an sample

Operational Qualification Test

Load Carrier (Washing Cart)

Visual observation;

Ensure spray free to rotate when load carrier is empty or full ;

Check alignment of load carrier for fitting the water inlet supply from WD

HTM 2030 Part 3 9.313 9.315
EN ISO 15883 6.7.1

Performance Qualification-
Cleaning Efficacy Test

Performance qualification-

Cleaning Efficacy Test – 1. Soil Test

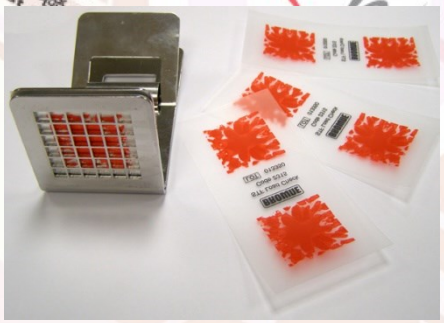
Test Soil applied to Chamber

Test Soil applied to Load Carrier

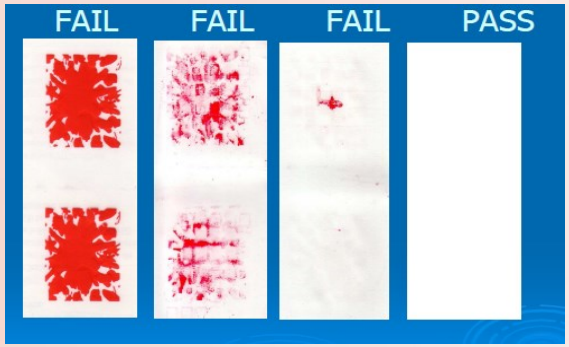
Performance qualification-

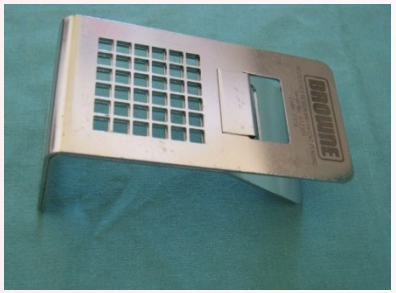
Cleaning Efficacy Test –

2. Load Check



Load check indicator is an indicator printed with a pattern off test soil on both sides off a plastic see-through substrate.



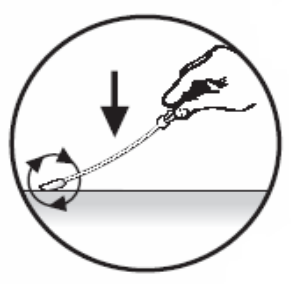


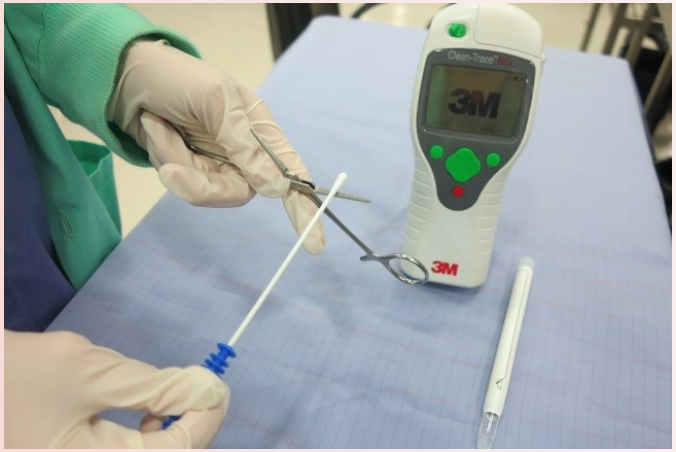
Performance qualification-

CLEANING EFFICACY TEST –

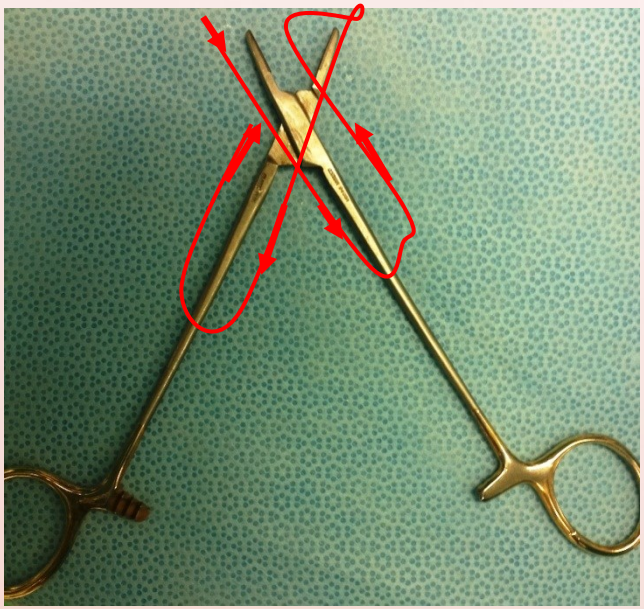
3. ATP SWAB TEST

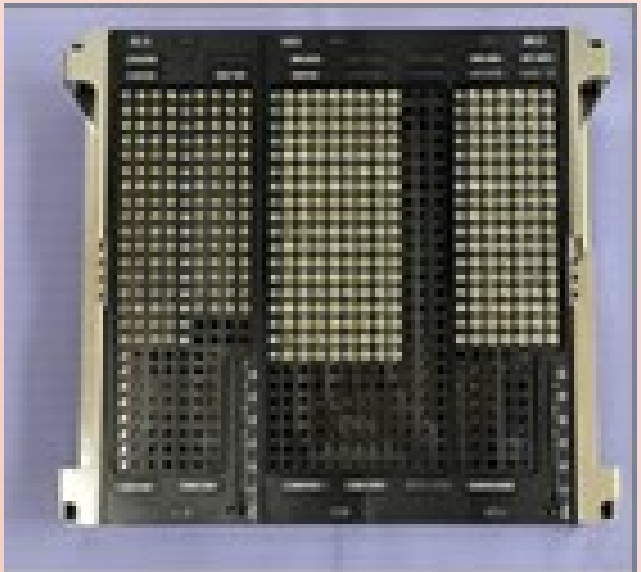
Swab → **Reaction – Click & Shake** → **Measure & Record**





Cleaning Efficacy Monitoring by ATP





Implantable Instruments

No.	Description	Decontamination description		Visual Cleanliness	RLU	
		Before	After		Before	After
1.	Box with lid for holding washers	✓ Manual wash	✓ With manual pre-cleanse and water jet before decontamination; ✓ Mini washer disinfector; ✓ With pre-soak gel sprayed; ✓ Standard cycle, without sonication.	Yes	404	34
2.	Guide wire			Yes	3028	49
3.	Measuring device			Yes	5341	34
4.	A.O. 40mm cannulated screw tray			Yes	634	20
5.	4mm screw			Yes	102	22
6.	LCP plate, 7-hole	✓ Manual wash	✓ With manual pre-cleanse before decontamination ✓ Automatic washer disinfector (B); ✓ With pre-soak gel sprayed; ✓ Standard cycle, without sonication.	Yes	686	24
7.	8-hole T plate (x41.151)			Yes	632	44
8.	8-hole T plate (x41.141)			Yes	617	22
9.	3.5mm screw (size 88)			Yes	88	37
10.	Screw tray inner cover			Yes	925	476

Quality Management System

VALIDATION AND ROUTINE CONTROL OF STEAM STERILIZER

Automatic Control Test (ACT)

Aim:

To show the operating cycle functions correctly as evidenced by the values of the cycle variables fitted to the sterilizer

Reference from EN 285 2006+A1 2008 7.1.5

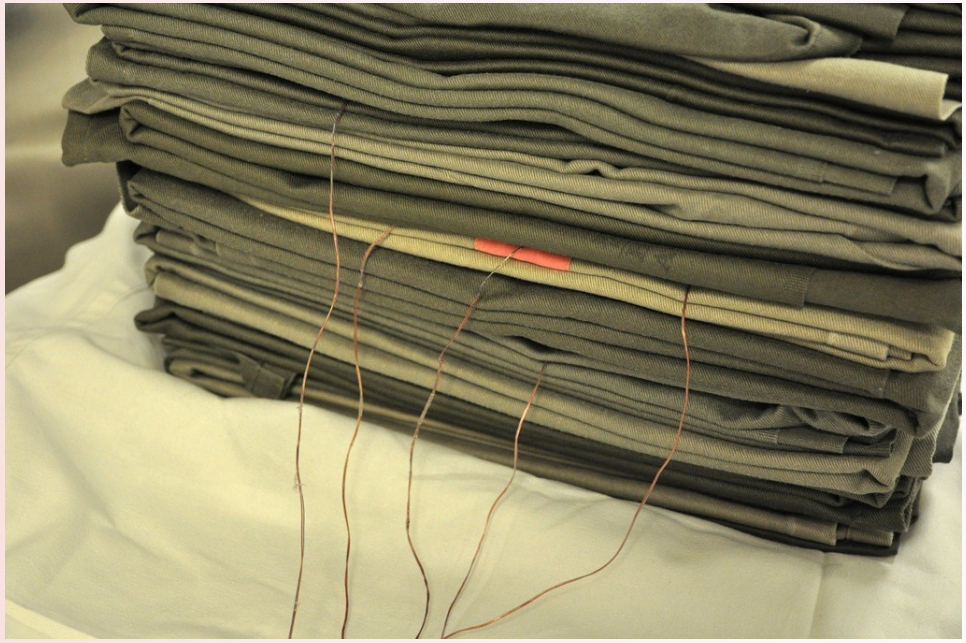
CFPP Part C 13205

Automatic Control Test of Washer Disinfector			
Washer Disinfector	WD B	Hospital	
Programme	P 2	TMH / POH / TSWH	
Test Date	20170201	Frequency of Validation	
Cycle Number	5531	■ Weekly	
Cycle Start Time	14:57:42	☐ Quarterly	
Cycle Finished Time	15:39:37	☐ Yearly	
Stage	**Reading Taken At**		**Reference**
Pre-Rinse	Time at Start	14:57:42	09:27:31
	Time at End	15:00:56	09:30:39
	Durtaion (Time)	00:03:14	00:03:08
	Holding Temperature (Average)	30.94 C	37.38 C
	Holding Pressure (Average)	261 mbar	174 mbar
Wash	Time at Start	15:00:57	09:30:40
	Time at End	15:11:32	09:41:38
	Durtaion (Time)	00:10:35	00:10:58
	Dosing Temperature	40.95 C	45.24 C
	Dosing Volume	201.30 ml	200.53 ml
	Holding Temperature (Average)	57.44 C	57.36 C
	Holding Pressure (Average)	248 mbar	185 mbar
Ultrasound	Time at Start		
	Time at End		
	Durtaion (Time)		
Rinse	Time at Start	15:11:34	09:41:40
	Time at End	15:14:24	09:44:36
	Durtaion (Time)	00:02:50	00:02:56
	Holding Temperature (Average)	50.84 C	53.09 C
	Holding Pressure (Average)	256 mbar	187 mbar
Thermal Disinfection	Time at Start	15:14:25	09:44:37
	Time at End	15:29:23	09:59:46
	Durtaion (Time)	00:14:58	00:15:09
	Holding Temperature (Average)	92.66 C	92.60 C
	Holding Pressure (Average)	189 mbar	143 mbar
	Holding Time	300 s	300 s

Thermometric Test (Small Load)

Aim:

To demonstrate that after the air removal stage of the sterilization cycle sterilizing conditions are obtained within the sterilizer chamber and test pack

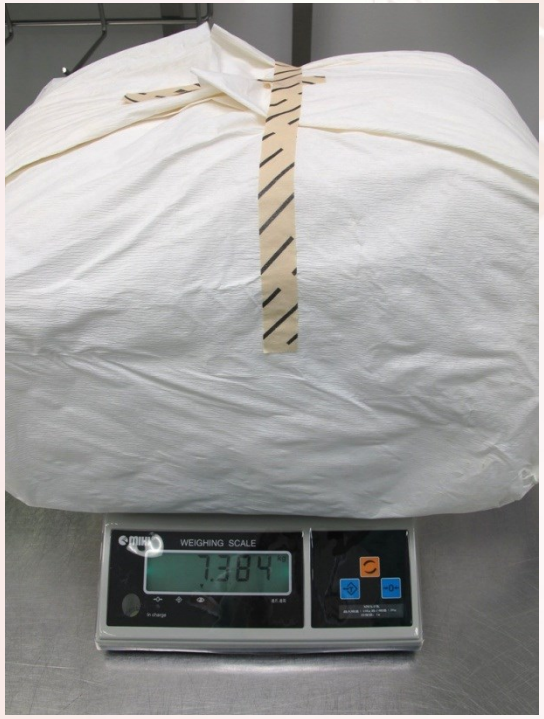


Reference from EN 285 2006+A1 2008 8.2.1.2, 16.1

CFPP Part C 13208

Load Dryness Test For textiles

Before Sterilization



After Sterilization

% Change of weight after sterilization:

(7.384 – 7.358) / 7.384 x 100% = 0.353%

Quality Management System

7. Measurement, Analysis and Improvement

- 7.1 Key Performance Indicator
- 7.2 Customer Satisfaction
- 7.3 Internal Audit
- 7.4 Monitoring and Measurement of Processes
- 7.5 Monitoring and Measurement of Product
- 7.6 Control of Non-conforming Products
- 7.7 Continuous Quality Improvement
  - 7.7.1 Corrective Action
  - 7.7.2 Preventive Action

Quality Management System

- **Feedback & Complaint**

  - Customer Care

  (i.e. complaints , customer feedback)

  - Immediate Action
  - Follow-up
  - Root Cause Analysis
  - Recommendation
  - Review
  - Management meeting

Report Mechanism of Nearly Missed Record

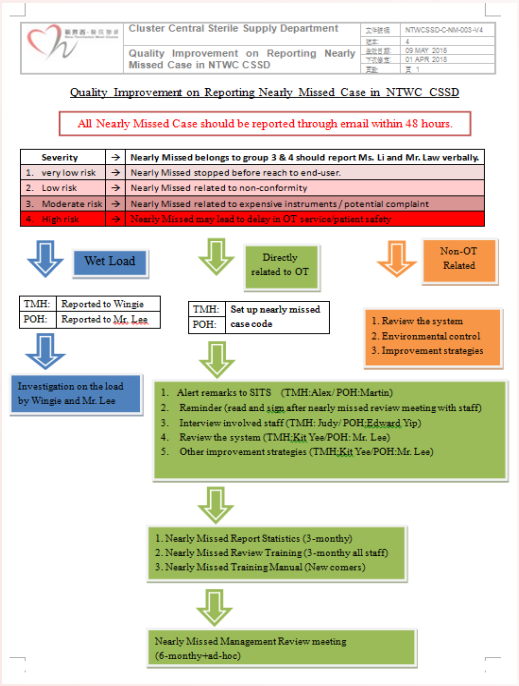
TMH CSSD Incident Record (2015)

Incident Category:		Related To:	Code	Severity		Follow-Up by
1. customer care	5. environmental defect	O= Direct Related OT	T14193P	VL=Very low risk		
2. non-conforming product	6. IOD	N= Non-OT Related	N/A	L=Low risk	L	
3. fault of machine or equipment	7. others	W= Wet Load	N/A	M=Moderate risk		Completed on:
4. shortage of supply		Incident Event No.		H=High risk		

Event No.	Date	Incident Details	Action Taken	Category	Recorded by
1		2015	Immediate Action: Root Cause: Recommendation: Final Review: Follow-up:	2	

Nearly Missed Case Reporting System

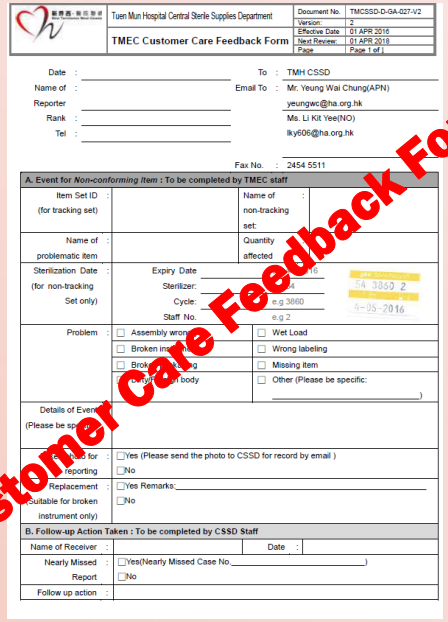
- Establish since 2009
- Under **"No Blame Culture"**
- Report on **Real Time**
- **Daily Report** to supervisors & management
- **Well-defined the Workflow** of Report Mechanism



Nearly Missed Case Reporting System

1.Channel of reporting

- Customer Feedback Form
- Email
- communicate verbally



Tuen Mun Hospital Central Sterile Supplies Department

TMEC Customer Care Feedback Form

Document No.: TMCSSD-D-QA-027-V2
Version: 2
Effective Date: 01 APR 2016
Next Review: 01 APR 2018
Page: 1 of 1

Date :
Name of Reporter :
Rank :
Tel :

To : TMH CSSD
Email To : Mr. Yeung Wai Chung(APN) yeungwc@ha.org.hk
Ms. Li Kit Yee(NO) lky606@ha.org.hk
Fax No. : 2454 5511

A. Event for *Non-conforming Item* : To be completed by TMEC staff

Item Set ID (for tracking set) :
Name of non-tracking set:
Name of problematic item :
Quantity affected :
Sterilization Date (for non-tracking Set only) :
Expiry Date :
Sterilizer: e.g 3860
Cycle: e.g 3860
Staff No. e.g 2
Problem :
☐ Assembly wrong
☐ Broken instrument
☐ Broken packaging
☐ Foreign body
☐ Wet Load
☐ Wrong labeling
☐ Missing item
☐ Other (Please be specific:)
Details of Event (Please be specific) :
Photo for reporting :
☐Yes (Please send the photo to CSSD for record by email)
☐No
Replacement (Suitable for broken instrument only) :
☐Yes Remarks:
☐No

B. Follow-up Action Taken : To be completed by CSSD Staff

Name of Receiver :
Date :
Nearly Missed Report :
☐Yes(Nearly Missed Case No.)
☐No
Follow up action :

Customer Care Feedback Form

2. Risk Stratification

1. very low risk	→	Nearly Missed stopped before reach to end-user.
2. Low risk	→	Nearly Missed related to non-conformity
3. Moderate risk	→	Nearly Missed related to expensive instruments / potential complaint
4. High risk	→	Nearly Missed may lead to delay in OT service/patient safety

Belonged to group 3 & 4 should be reported to Unit In-charge verbally.

1: Very Low Risk
2. Low Risk
3. Moderate Risk
4. High Risk

Nearly Missed Case Reporting System

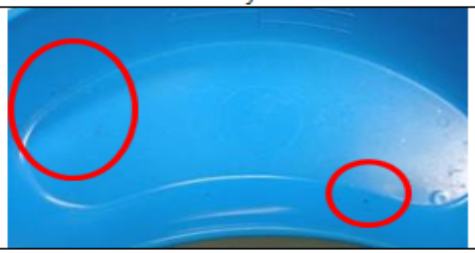
3. After Investigation → Writing Report

Supervisor

Stratification

TMH CSSD Nearly Missed Case Record (2016)

Nearly Missed Case Category:		Related To:	Code	Severity		Follow-Up by
1. customer care	5. environmental defect	O= Direct Related OT	T16029D	VL=Very low risk		Mr. Lee
2. non-conforming product	6. IOD	N= Non-OT Related	N/A	L=Low risk	L	Completed on:
3. fault of machine or equipment	7. others	W= Wet Load	N/A	M=Moderate risk		Report was sent to OT
4. shortage of supply	8. fault of facility	Case No. 20160206¹T		H=High risk		

Event No.	Date	Case Details	Action Taken	Category	Recorded by
2	03/02/2016 (WED)	**20160206T- Stain was found in S42X** Around 11:15, OT2 stated that some stain was found in Plastic Kidney dish 20cm and Plastic Kidney dish 25cm.  Plastic Kidney dish 25cm  Brown stain was found in Plastic Kidney dish 20cm	**Immediate Action:** ● CSSD Mr. Ken Yip (EO II) was informed. ● The captioned set was returned to CSSD for re-processing. **Root cause:** Impure Steam Supply ● It probably related to the impure steam supply rather than human error. ● Similar phenomenon had happened befo… and impure steam supply might be the root cause to facilitate the case. **Recommendation:** ● Keeping the related records for further analysis. ● Steam quality problem shall be feedback to EMSD for investigation. **Follow Up:**	2	Cherry

Topic

Immediate Action

Recorder

Root cause

Recommendation

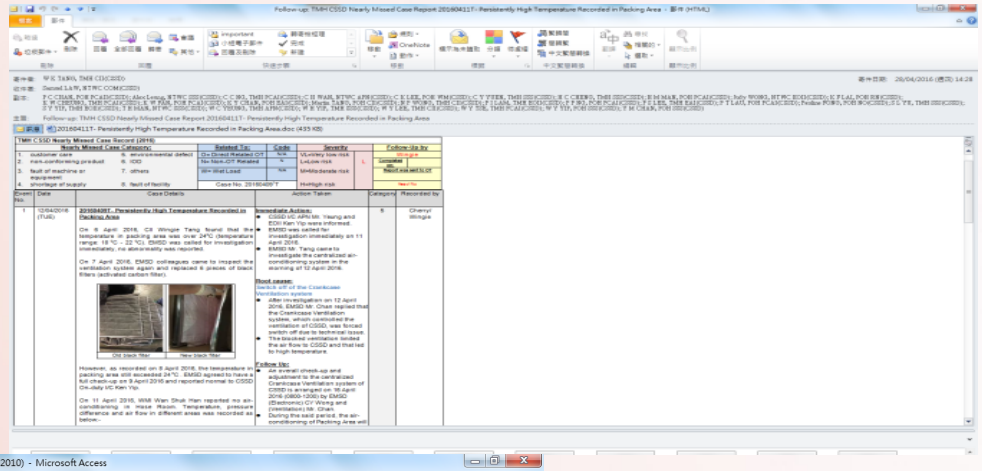
Follow Up

Content

Nearly Missed Case Reporting System

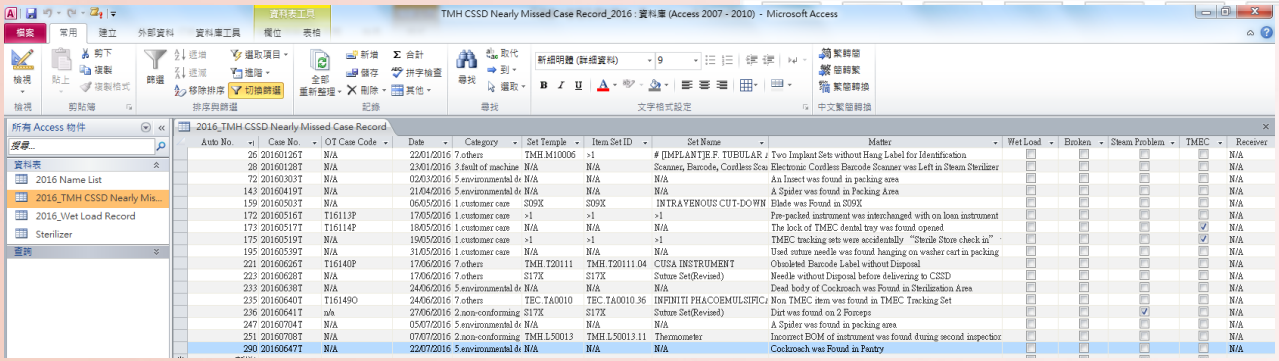
4. Reporting

- Verification by supervisor
- All Nearly Missed Case should be reported through email within 48 hours.



5. Recording

- Database for recording



Nearly Missed Case Reporting System

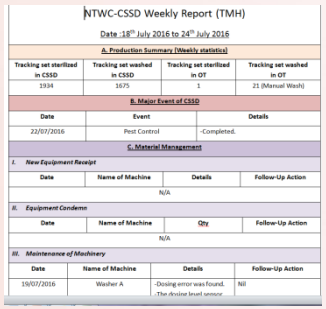
Nearly Missed Case Reporting System

6. Follow Up(FU) Action

a) Training

Quarterly Review Session with Packers

b) All outstanding FU should be recorded in weekly report in order to alert responsible staff to follow up.



NTWC-CSSD Weekly Report (TMH)

Date :18th July 2016 to 24th July 2016

A. Production Summary [Weekly statistics]

Tracking set sterilized in CSSD	Tracking set washed in CSSD	Tracking set sterilized in OT	Tracking set washed in OT
1934	1675	1	21 (Manual Wash)

B. Major Event of CSSD

Date	Event	Details
22/07/2016	Pest Control	-Completed.

C. Material Management

I. New Equipment Receipt

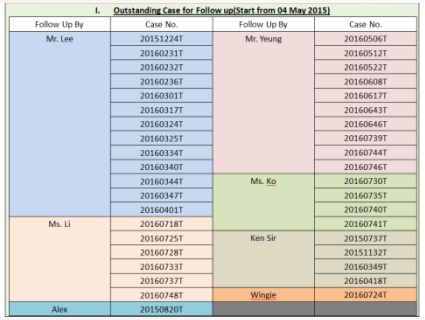
Date	Name of Machine	Details	Follow-Up Action
N/A			

II. Equipment Condemn

Date	Name of Machine	Qty	Follow-Up Action
N/A			

III. Maintenance of Machinery

Date	Name of Machine	Details	Follow-Up Action
19/07/2016	Washer A	-Dosing error was found. -The dosing level sensor	Nil



I. Outstanding Case for Follow up(Start from 04 May 2015)

Follow Up By	Case No.	Follow Up By	Case No.
Mr. Lee	20151224T	Mr. Yeung	20160506T
	20160231T		20160512T
	20160232T		20160522T
	20160236T		20160608T
	20160301T		20160617T
	20160317T		20160643T
	20160324T		20160646T
	20160325T		20160739T
	20160334T		20160744T
	20160340T		20160746T
	20160344T	Ms. Ko	20160730T
	20160347T		20160735T
	20160401T		20160740T
Ms. Li	20160718T		20160741T
	20160725T	Ken Sir	20150737T
	20160728T		20151132T
	20160733T		20160349T
	20160737T		20160418T
	20160748T	Wingie	20160724T
Alex	20150820T		

c) Management Review

Management Review Meeting

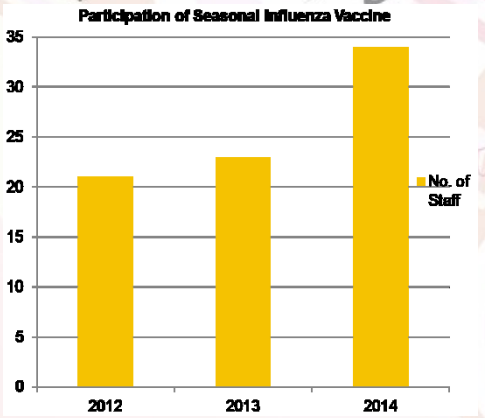
◆Members: All supervisors & management of CSSD

◆Frequency: Every 3 months

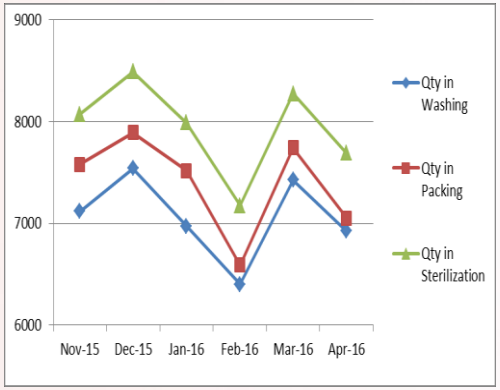
7. Measurement, Analysis and Improvement
-7.1 Key Performance Indicator

✓ Indicator for Management Review & Audit

No	KPI	Detail
2	Reprocessed fast tracked instrument service requested	No of reprocessed fast tracked instrument and compliance rate
4	Turned around time	TMOT: high tem; low temp TMEC: inst
6	Overtime record	No of overtime and people
8	Finished good issue (except tracking set)	Quantity

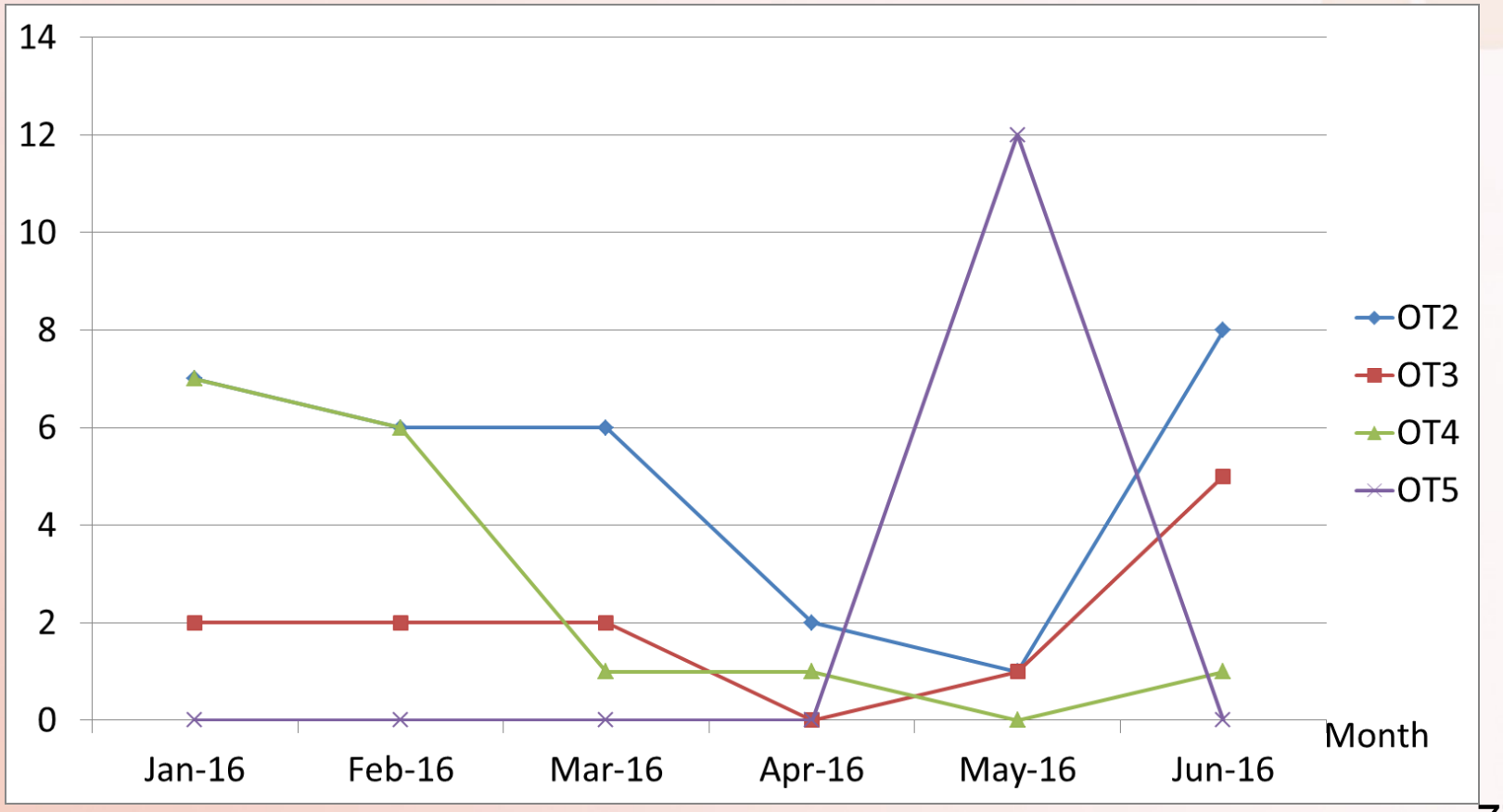


Reprocessed Instrument Set
(Nov 2015- April 2016)



Key Performance Indicator (KPI)

TMHCSSD Reprocessed Fast Tracked Instrument Service Requested
(Jan - June 2016)



Content

A. Introduction of Central Sterile Supplies Department

B. Hong Kong Experience of Hospital Accreditation

C. Sterilization Service Revolution in Tuen Mun Hospital

D. Quality Management System for Reprocessing Reusable Medical Devices in Hospital

E. Improvement in Corporate Level

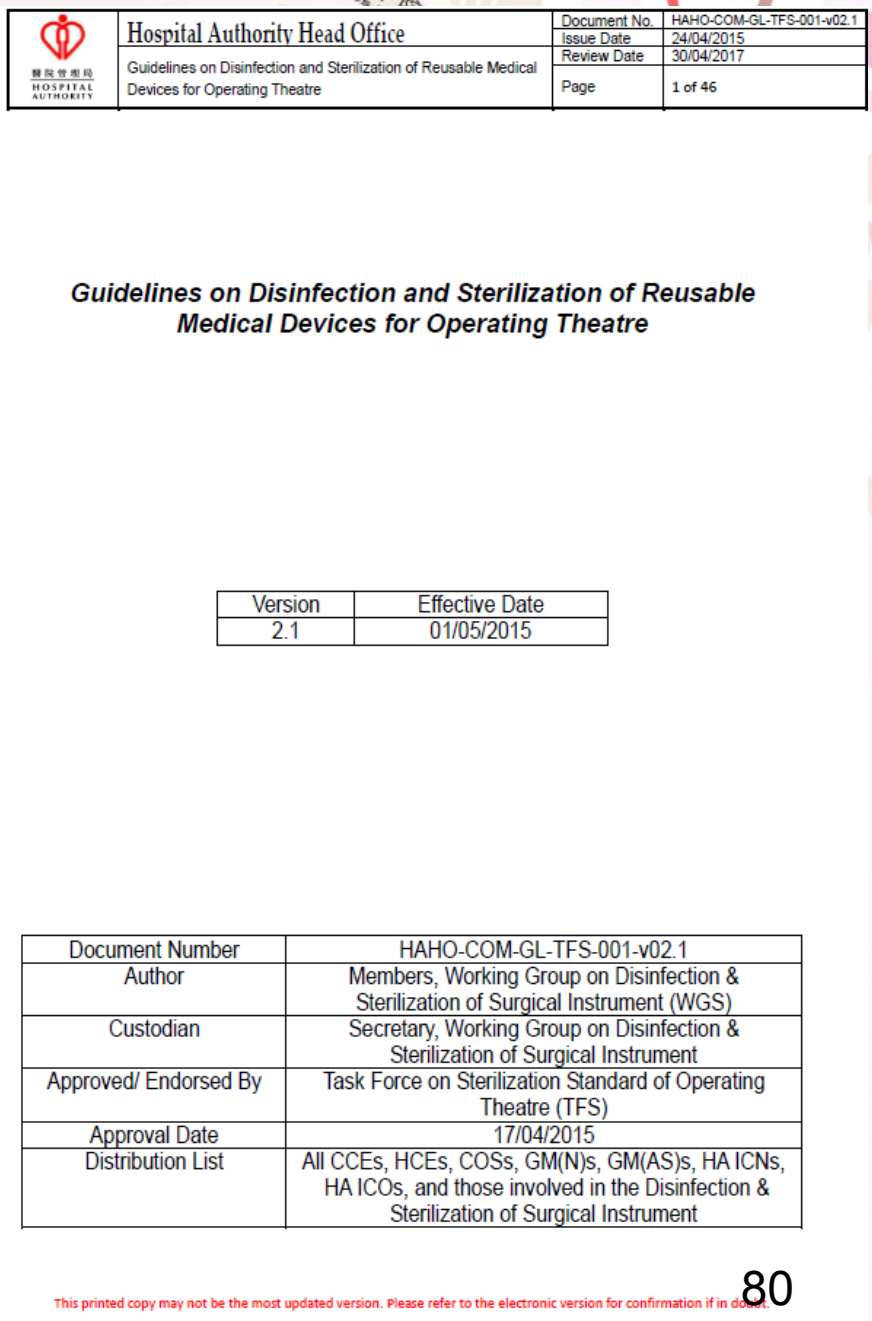
Improvement in Corporate Level

1. Task Force on Sterilization Standard of Operating Theatre
   - Setting up Governance structure
   - Development of Tracking and Tracing System
   - Demarcation for Dirty and Clean Area
   - Development of Guidelines on Sterilization
2. Service Advisory Group (Sterile Supply Service) under nursing profession
   - Development of operation standard in sterilization practice
   - Provision of advisory role whenever required
3. Phase out linen wrapper by disposable one meeting ISO 11607

Corporate Level

4. Guidelines Development

- Meet with international standard of practice
- Guide against construction requirement of CSSD
- Guide against the Quality management system in the reprocessing center



Hospital Authority Head Office	Document No.	HAHO-COM-GL-TFS-001-v02.1
	Issue Date	24/04/2015
Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre	Review Date	30/04/2017
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Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre

Version	Effective Date
2.1	01/05/2015

Document Number	HAHO-COM-GL-TFS-001-v02.1
Author	Members, Working Group on Disinfection & Sterilization of Surgical Instrument (WGS)
Custodian	Secretary, Working Group on Disinfection & Sterilization of Surgical Instrument
Approved/ Endorsed By	Task Force on Sterilization Standard of Operating Theatre (TFS)
Approval Date	17/04/2015
Distribution List	All CCEs, HCEs, COSs, GM(N)s, GM(AS)s, HA ICNs, HA ICOs, and those involved in the Disinfection & Sterilization of Surgical Instrument

Corporate Level

5. Development of Corporate Surgical Instrument Tracking System (SITs) and Roll out to 22 HA hospitals

Print Date: 2014-04-08 15:49:34

Item Set Count Sheet

Set ID: POH.T00001.02 (Version No: 1)

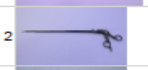
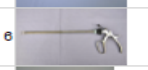
Set Name: EXTRA SURG LAP. SET (CHOLECYSTECTOMY)

Legacy Set ID: X002

Locator: POH.C.SG.7.A1

Packing Warning :
P1101SM1:必須留意"廁所板"上方是否緊附一條鐵片，如沒有請立即通知上司;;P12008P :包裝員及審核員必須核對物品上之編碼，如發現物品上之編碼與 CHECKLIST上列印之編碼不符，包裝員必須立刻通知上司。;;T0001 :如儀器品牌是KARL STORZ (K.S)請檢查開口較位的SCREW CAP

Count Sheet

1		1	FORCEPS,GRASPING,BABCOCK,10X330MM,47MM JAWS,MONOPOLAR,ERGO HANDLE,OLYMPUS	A65050A	A65050A = A66050A+A60900A +A60101A
2		1	FORCEPS,DISSECTING,MARYLAND,'C',10X330MM,30MM JAWS,TAPERED,MONOPOLAR,ERGO HANDLE,OLMYPUS	A66310A/A60901A/A60101A	CHECK CAP, 必須配上前幼後粗的黑膠管& 開口較位螺絲是否完整
3		1	FORCEPS,GRASPING,BULLET NOSE,5X310MM,AESCULAP (PO735R),W/RATCHET HANDLE (PO951R),AESCULAP	PO735R/PM973R/PO951R	PUT ON PROTECTIVE CAP
4		1	APPLICATOR,PDS LIGACLIP,'L',AP4010S		CHECK SCREW X 2 CHECK CAP X 1
5		1	APPLICATOR,METAL CLIP 'MEDIUM L',10MM,EL314		CHECK SCREW X 2
6		1	APPLICATOR,PDS LIGACLIP,'MEDIUM L',AP3010S		CHECK SCREW X 2 CHECK CAP X 1
7		1	ELECTRODE,SPATULATED,LAP.,A6294		CHECK RING
8		1	FORCEPS,GRASPING,CLAW,GALL BLADDER,10X330MM,45MM JAWS,MONOPOLAR,ERGO HANDLE,OLYMPUS	A66020A/A60900A/A60101A	CHECK PROTECTIVE CAP
9		2	TROCAR & CANNULA,BLUNT,11MM,OLYMPUS (S.O.5)		CHECK RING, VALUE OPEN & 檢查「廁所板」鐵夾
10		1	REDUCER,LONG,5MM,W/CAP,A5610 (S.O.2)		CHECK CAP
11		1	REDUCER,SHORT(S.O.3)		CHECK CAP
12		1	PLASTIC KIDNEY DISH 20CM, BOTTOM WITH HOLES		

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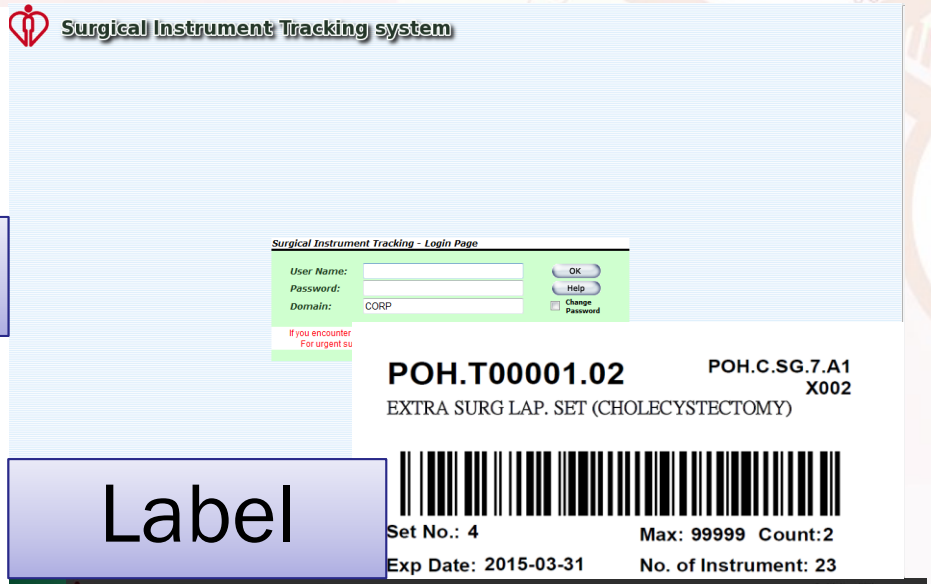

Label

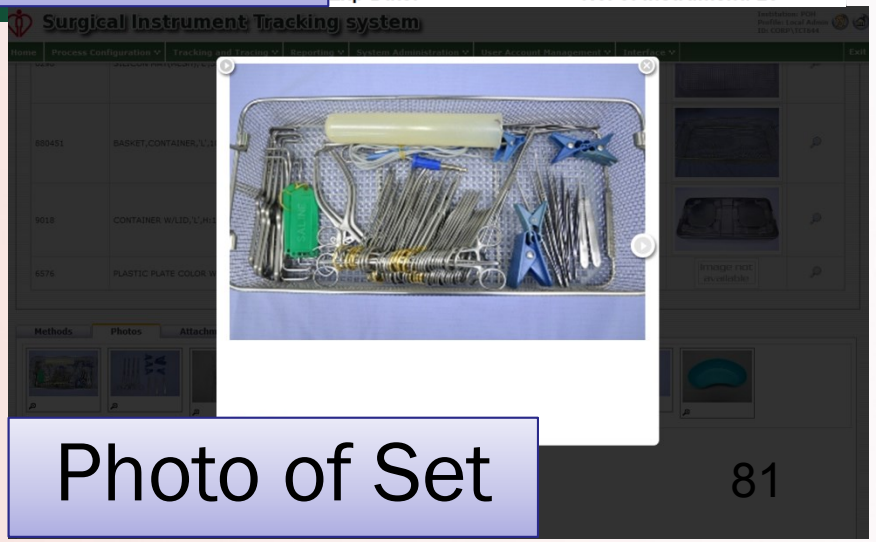

Photo of Set

Conclusion

- To ensure the reprocessing/production process of medical devices meeting the best practice.

- Monitoring the effectiveness of the sterilization procedure to prevent cross infection
  - Quality Management System
  - Environmental Control
  - Process
  - Staff education
- Ensure patient and staff safety

With collaborated effort !

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End

Thank you for your attention