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

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

A. Introduction of Central Sterile Supplies Department
A. Introduction of Central Sterile Supplies Department

**Traditional CSSD**

Reprocessing of Linen Items
A. Introduction of Central Sterile Supplies Department

Traditional CSSD

Reprocessing of Reusable Medical Device and Ward Procedure Set
A. Introduction of Central Sterile Supplies Department

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
A. Introduction of Central Sterile Supplies Department

**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
A. Introduction of Central Sterile Supplies Department

Scope of Services of **TSSU**

To reprocess operating theatre surgical instruments
A. Introduction of Central Sterile Supplies Department

Scope of Services of TSSU

To reprocess operating theatre surgical instruments
Content

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E. Improvement in Corporate Level
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
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
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
**Content**

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C. **Sterilization Service Revolution in Tuen Mun Hospital**

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E. Improvement in Corporate Level
C. Sterilization Service Revolution in Tuen Mun Hospital

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
C. Sterilization Service Revolution in Tuen Mun Hospital

Design and Management of new CSSD

- Quality Systems
  - Medical Devices: EN ISO 13485:2003

- Quality Manual Policies and procedures

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

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

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

Reference to HA Guidelines on Disinfection & Sterilization of Reusable Medical Devices for OT
C. Sterilization Service Revolution in Tuen Mun Hospital

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
C. Sterilization Service Revolution in Tuen Mun Hospital

① Infrastructure Requirement

Demarcation of Clean and Dirty Area

Decontamination area

Air-tight Panel

Negative pressure
1. Air-tight Ceiling
2. Positive Pressure 10 – 20 Pascal
3. ISO 14644 Class 8 Clean room standard
4. Lighting with 700 lux
C. Sterilization Service Revolution in Tuen Mun Hospital

② Equipment Requirement Standards for Reference

Standards of Steam Sterilizer

ISO 17665 & EN 285
C. Sterilization Service Revolution in Tuen Mun Hospital

② Equipment Requirement Standards for Reference

Standard of Hydrogen Peroxide Sterilizer

STERRAD 100NX

STERRAD 100S

ISO 14937
C. Sterilization Service Revolution in Tuen Mun Hospital

② Equipment Requirement

Standards for Reference

Standards of Washer Disinfector

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.
C. Sterilization Service Revolution in Tuen Mun Hospital

New Scopes of Service

2. Fade Out Linen Item

Use disposable drapes
C. Sterilization Service Revolution in Tuen Mun Hospital

**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**
C. Sterilization Service Revolution in Tuen Mun Hospital

**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
C. Sterilization Service Revolution in Tuen Mun Hospital

New Scopes of Service

5. Topping Up (Auto-Refill System)

Bar Code Scanner

- Bar Code label
- Check Quantity

Generate a report and prepare refill items

Synchronize the data of portable scanner to computer
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

Centralization within a hospital

TSSU

CSSD
C. Sterilization Service Revolution in Tuen Mun Hospital

Centralization of Sterile Supply Services within NTWC
Content

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

E. Improvement in Corporate Level
Infection Control in Hospitals

Importance of Decontamination Practices in Infection Control

Disinfection
Cleaning
Sterilization

Education
Surveillance
Hand hygiene
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

Quality Assurance

D. QMS for Reprocessing Reusable Medical Devices in Hospital
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
D. QMS for Reprocessing Reusable Medical Devices in Hospital

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
## Credential – Qualification of Staffs

<table>
<thead>
<tr>
<th>Range of Duties</th>
<th>WMII/ GSA</th>
<th>WMII/ TSA</th>
<th>Artisan/ TSA</th>
<th>SSS &amp; RN</th>
<th>NO</th>
<th>COM</th>
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<tbody>
<tr>
<td>Infection Control</td>
<td>✓</td>
<td>✓</td>
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<td>Understanding of quality systems</td>
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<td>✓</td>
<td>✓</td>
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<td>Basic Concept of Tracking and Traceability</td>
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<td>Collect and handle soil instrument set</td>
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<td>✓</td>
<td>✓</td>
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<td>Recognize Instrument Set</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Assemble Instrument Set, Linen Pack and Dressing Pack</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>Assemble High Level Disinfection Item</td>
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<td>Operate Sterilizer</td>
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<td>✓</td>
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<td>✓</td>
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<td>Basic Stock Control</td>
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<td>Basic IT skills</td>
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<td>Tracking System</td>
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<td>Environmental Monitoring</td>
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<td>Quality Sampling</td>
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<td>✓</td>
<td>✓</td>
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<td>Supervise Staff</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Monitor Stock level</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>Handle Customer Complaint</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>Internal Auditing</td>
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<td>X</td>
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<tr>
<td>Train staff in special duties</td>
<td>X</td>
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<td>✓</td>
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<tr>
<td>Procurement</td>
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<td>✓</td>
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<td>Recruitment / Interview</td>
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<td>X</td>
<td>X</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Resources Management</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
</tr>
<tr>
<td>Liaison Duties</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>✓</td>
</tr>
</tbody>
</table>
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
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

<table>
<thead>
<tr>
<th>% staff surveyed (29)</th>
<th>Surprise check (Pre-wash)</th>
<th>Immediately retest (Pro-wash)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>85% = 29 (surveyed staff) 34 (packing staff)</td>
</tr>
</tbody>
</table>

**Relative Light Unit (RLU) detected on staff strong hand (慣用手)**

<table>
<thead>
<tr>
<th>Range (29)</th>
<th>404 - 30332</th>
<th>86 - 3643</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max (29)</td>
<td>30332</td>
<td>3643</td>
</tr>
<tr>
<td>Min (29)</td>
<td>404</td>
<td>86</td>
</tr>
<tr>
<td>Median (29)</td>
<td>2844</td>
<td>410</td>
</tr>
</tbody>
</table>

**Average RLU**

<table>
<thead>
<tr>
<th>All staff (29)</th>
<th>5351</th>
<th>755</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (25)</td>
<td>4953</td>
<td>548</td>
</tr>
<tr>
<td>Male (4)</td>
<td>6343</td>
<td>1594</td>
</tr>
<tr>
<td>Entry before 2003 (10)</td>
<td>3019</td>
<td>338</td>
</tr>
<tr>
<td>Entry after 2003 (19)</td>
<td>6365</td>
<td>967</td>
</tr>
<tr>
<td>a. Entry between 2003 – 2011 (&gt;1 ICN course attended) (7)</td>
<td>6365</td>
<td>420</td>
</tr>
<tr>
<td>b. Entry: less than 18 months (very new staff ≠1 ICN course attended) (12)</td>
<td>6785</td>
<td>1376</td>
</tr>
</tbody>
</table>
5. Infection Control

5.5 Environmental Control

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

*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>
<thead>
<tr>
<th>ISO classification number (N)</th>
<th>Maximum concentration limits (particles/m³ 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]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0,1 μm</td>
</tr>
<tr>
<td>ISO Class 1</td>
<td>10</td>
</tr>
<tr>
<td>ISO Class 2</td>
<td>100</td>
</tr>
<tr>
<td>ISO Class 3</td>
<td>1 000</td>
</tr>
<tr>
<td>ISO Class 4</td>
<td>10 000</td>
</tr>
<tr>
<td>ISO Class 5</td>
<td>100 000</td>
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<td>ISO Class 6</td>
<td>1 000 000</td>
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<tr>
<td>ISO Class 7</td>
<td></td>
</tr>
<tr>
<td>ISO Class 8</td>
<td></td>
</tr>
<tr>
<td>ISO Class 9</td>
<td></td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Floor plan of 15 packing locations (217m2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E機尾</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>7</td>
</tr>
<tr>
<td>10</td>
</tr>
<tr>
<td>13</td>
</tr>
</tbody>
</table>

爐位:門

喉房
潔具房
抽風櫃

<table>
<thead>
<tr>
<th>Particle Size (um)</th>
<th>0.3</th>
<th>0.5</th>
<th>1.0</th>
<th>3.0</th>
<th>5.0</th>
<th>10.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration (Particle count / m3 of air)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td>504</td>
<td>101</td>
<td>24</td>
<td>4</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Max</strong></td>
<td>1196</td>
<td>296</td>
<td>63</td>
<td>6</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>
5.5 Environmental Control

Pressure Difference Monitoring of an IAP room

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

Direction of Air Flow

- Decon -ve pressure
- Sterile Store +ve pressure
- Sterilization Area ++ve pressure
- Plantroom -ve
- IAP +++ ve pressure
- Hose
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
6. Product Realization (Production Standard)
6.3 Validation System of Decontamination Equipment

Performance Qualification - Cleaning Efficacy Test

Routine testing
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

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

VALIDATION AND ROUTINE CONTROL OF STEAM STERILIZER
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
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:

\[
\frac{(7.384 - 7.358)}{7.384} \times 100\% = 0.353\%
\]
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](image)
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

D. QMS for Reprocessing Reusable Medical Devices in Hospital
D. QMS for Reprocessing Reusable Medical Devices in Hospital

Nearly Missed Case Reporting System

1. Channel of reporting
   - Customer Feedback Form
   - Email
   - communicate verbally

2. Risk Stratification

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. very low risk</td>
<td>Nearly Missed stopped before reach to end-user.</td>
</tr>
<tr>
<td>2. Low risk</td>
<td>Nearly Missed related to non-conformity</td>
</tr>
<tr>
<td>3. Moderate risk</td>
<td>Nearly Missed related to expensive instruments / potential complaint</td>
</tr>
<tr>
<td>4. High risk</td>
<td>Nearly Missed may lead to delay in OT service/patient safety</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Event No.</th>
<th>Date</th>
<th>Case Details</th>
<th>Topic</th>
<th>Immediate Action</th>
<th>Recorder</th>
<th>Root cause</th>
<th>Recommendation</th>
<th>Follow Up</th>
<th>Stratification</th>
<th>Supervisor</th>
</tr>
</thead>
</table>
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

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.

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

<table>
<thead>
<tr>
<th>No</th>
<th>KPI</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>KPI</td>
<td>Detail</td>
</tr>
<tr>
<td>2</td>
<td>Reprocessed fast tracked instrument service requested</td>
<td>No of reprocessed fast tracked instrument and compliance rate</td>
</tr>
<tr>
<td>3</td>
<td>Daily Reprocessed fast tracked instrument</td>
<td>No of reprocessed fast tracked instrument in day end</td>
</tr>
<tr>
<td>4</td>
<td>Turned around time</td>
<td>TMOT: high tem; low temp TMEC: inst</td>
</tr>
<tr>
<td>5</td>
<td>Sick leave</td>
<td>1-2 day; 3-6 day; &gt;7 day</td>
</tr>
<tr>
<td>6</td>
<td>Overtime record</td>
<td>No of overtime and people</td>
</tr>
<tr>
<td>8</td>
<td>Finished good issue (except tracking set)</td>
<td>Quantity</td>
</tr>
</tbody>
</table>
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
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
E. Improvement in Corporate Level

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

**Item Set Count Sheet**

- **Set ID:** POH.T0000.02 (Version No: 1)
- **Legacy Set ID:** X002
- **Set Name:** EXTRA SURG. LAP. SET (CHOLECYSTECTOMY)
- **Location:** POH.C.SG.7.A1

**Photo of Set**

**Label**

- **Set No.:** 4
- **Max.:** 99999
- **Count:** 2
- **Exp Date:** 2015-03-31
- **No. of Instrument:** 23
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!
Mr. LAW Tat Hong Samuel
Cluster Operations Manager
CSSD Tuen Mun Hospital, CSSD Pok Oi Hospital, CSSD Tin Shui Wai Hospital
New Territories West Cluster, Hong Kong
Email: lawth@ha.org.hk
Tel: (852)-24685315

End

Thank you for your attention