Decontamination and Reprocessing of Medical Devices in Hospital Authority: Standard and Practice

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Sterilization of Surgical Instruments: From Basic to Advancement

30 September 2021

Content

- Key Driver for Changes
- Where is HA now?
- The Way Forward


CHANGE

Key Driver for Changes

- The Australian Council on Healthcare Standards (ACHS) Accreditation Survey in December 2009
- Issues required urgent attention
  - High usage of flash sterilization across hospitals
  - Lack of clear segregation of clean and dirty zones
  - Inconsistency in service governance
  - Variations in the technical standards and requirements applied
  - Lack of effective tracking and tracing of surgical instrument

Task Force on Sterilization Standard of Operating Theater (OT)

Task Force on Sterilization Standard of OT

Service improvement focus and targets

- Eliminate flash sterilization as routine practice
- Eliminate the use of Cidex for rigid endoscope for entry into sterile body cavities
- Develop corporate-wide tracking and tracing system
- Conduct a consultancy study to propose plan to enhance disinfection and sterilization of reusable surgical instruments in HA

External Consultancy Study 2011/12

Key Recommendations in the Areas

A. Governance Structure
B. Corporate Guidelines on Disinfection and Sterilization
C. Corporate-wide Instrument Tracking and Tracing System
D. Linen Wrappers and Drapes

A. Governance Structure

- High-level governance structure to sustain the enhancement and quality assurance of sterilization
- A cluster sterilisation lead responsible for operational governance and QA
- Define a reporting line (e.g. to the CCE / deputy CCE). Clear responsibility and accountability
- A centralized CSSD to consolidate the management of instrument reprocessing and other sterilization services
- Service managed by a skilled, competent and adequately staffed team

B. Corporate Guidelines on Disinfection and Sterilization

- Revise HA Guidelines on the Disinfection and Sterilization of Reusable Medical Devices for OT
- Include recommendations concerning environmental considerations for facilities, such as ISO Class 8, to ensure clean rooms and air quality standards

C. Corporate-wide Instrument Tracking and Tracing System

- Develop a corporate-wide electronic surgical instrument tracking and tracing system

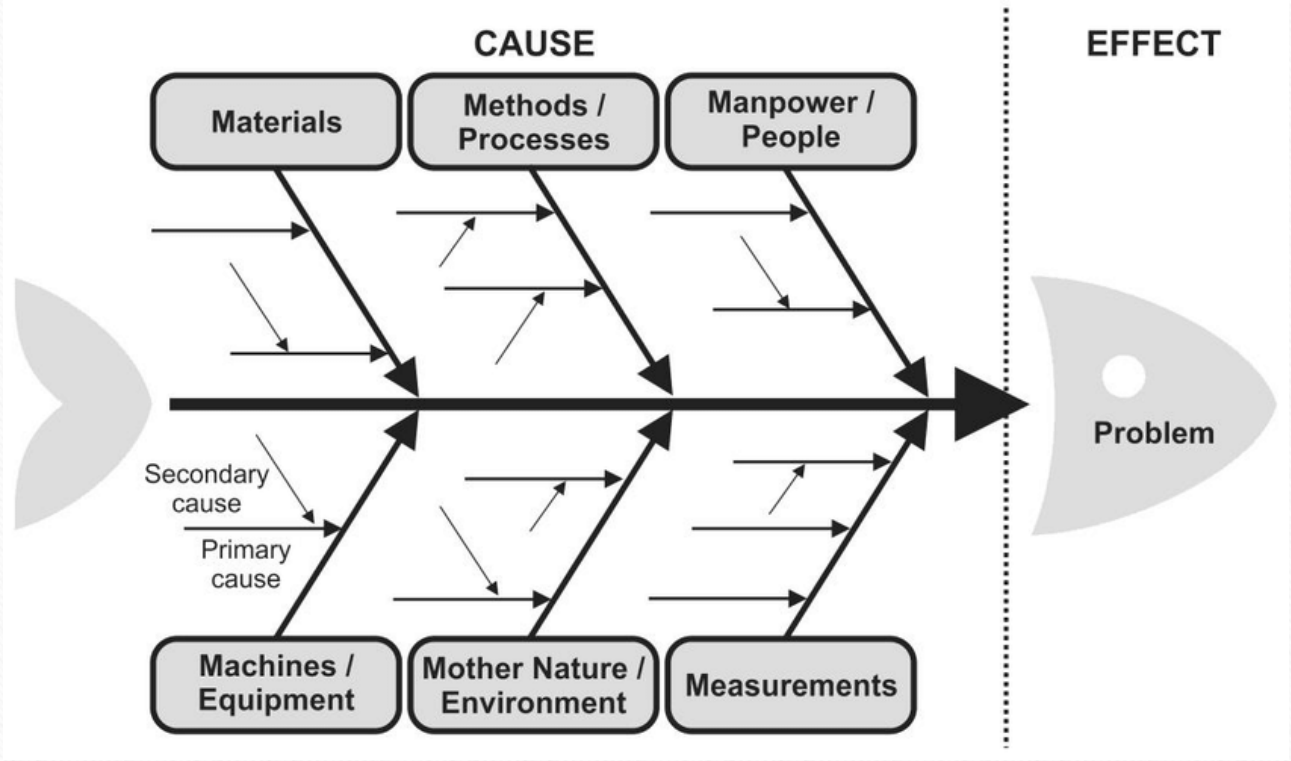
D. Linen Wrappers and Drapes

- Replace linen wrappers and drapes by disposable

Internal Audit on Sterilization and Disinfection 2014/15

- Review the compliance of CSSDs with the External Consultancy Report and the Guidelines
- Total 20 hospitals with CSSDs audited
- All CSSDs met the mandatory requirements

Where is HA Now?



Where is HA Now?

A. Trained People
B. Improved Environment
C. Upgraded Machines / Equipment
D. Up-to-Standard Materials
E. Methods / Processes in accordance with international standards
F. Measurements for Improvement

A. Trained People
Service Core Group (Sterile Supply Services)

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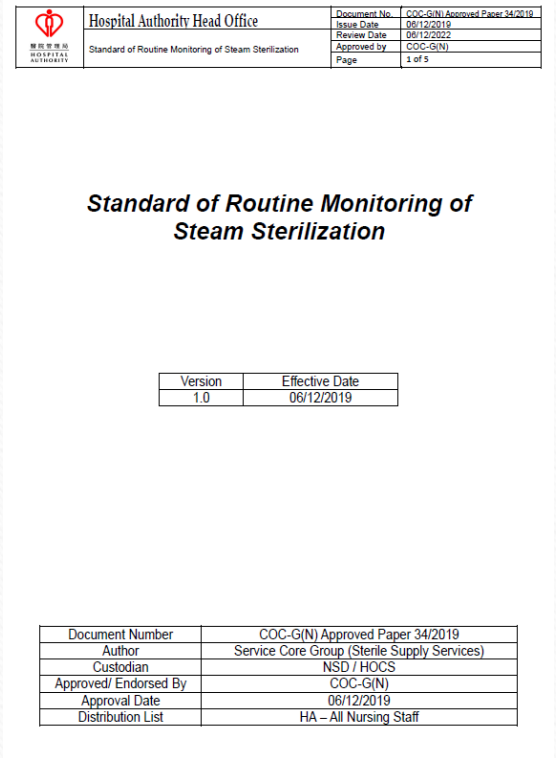


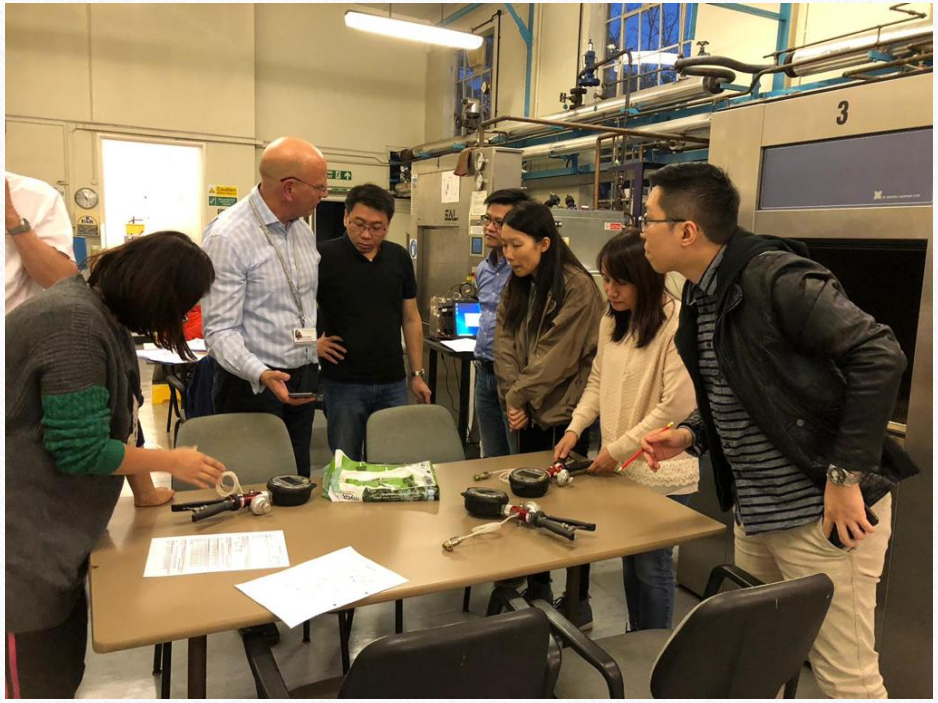
Hospital Authority Head Office	Document No.	COC-G(N) Approved Paper 34/2019
	Issue Date	06/12/2019
Standard of Routine Monitoring of Steam Sterilization	Review Date	06/12/2022
	Approved by	COC-G(N)
	Page	1 of 5

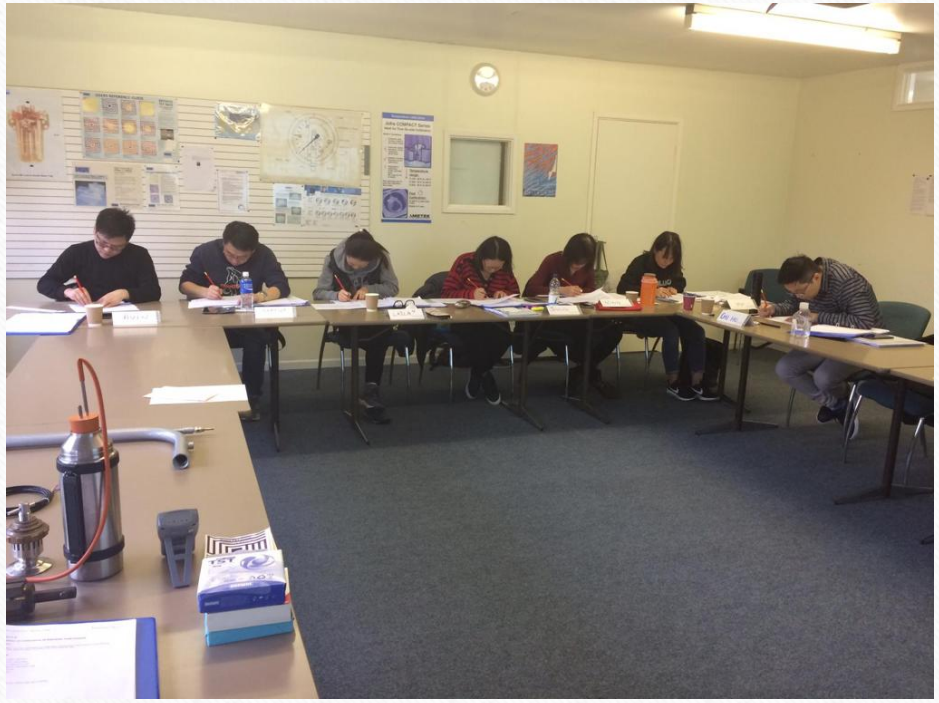
Standard of Routine Monitoring of Steam Sterilization

Version	Effective Date
1.0	06/12/2019

Document Number	COC-G(N) Approved Paper 34/2019
Author	Service Core Group (Sterile Supply Services)
Custodian	NSD / HOCS
Approved/ Endorsed By	COC-G(N)
Approval Date	06/12/2019
Distribution List	HA – All Nursing Staff

A. Trained People
Overseas Corporate Scholarship Programs





A. Trained People
Commissioned Training Courses

B. Improved Environment

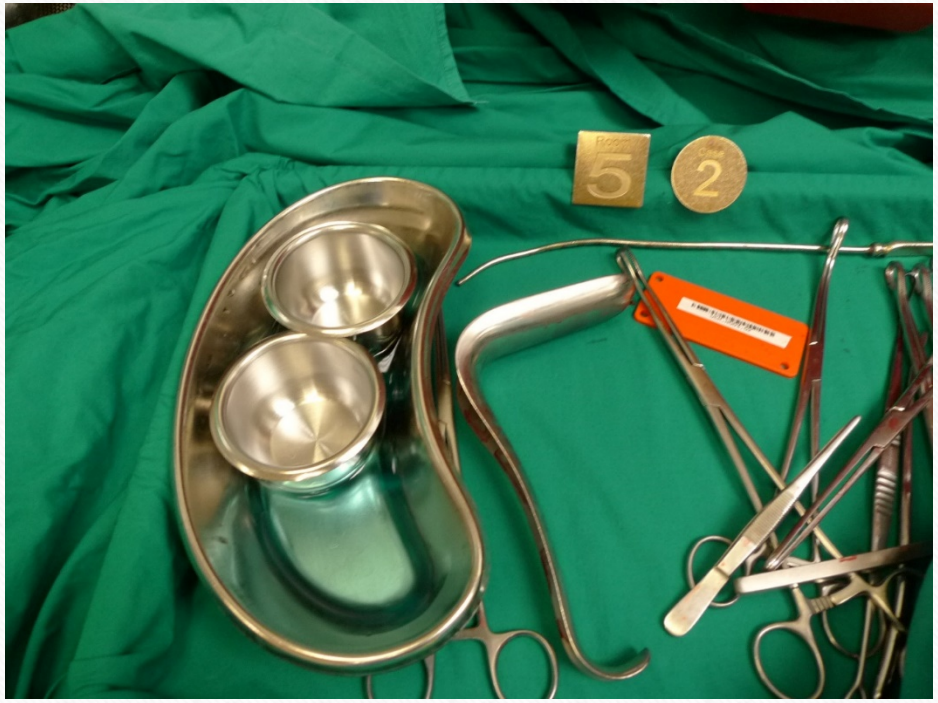
- Reprocessing facilities should be designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities
- All newly built or renovated units should follow the facility requirements

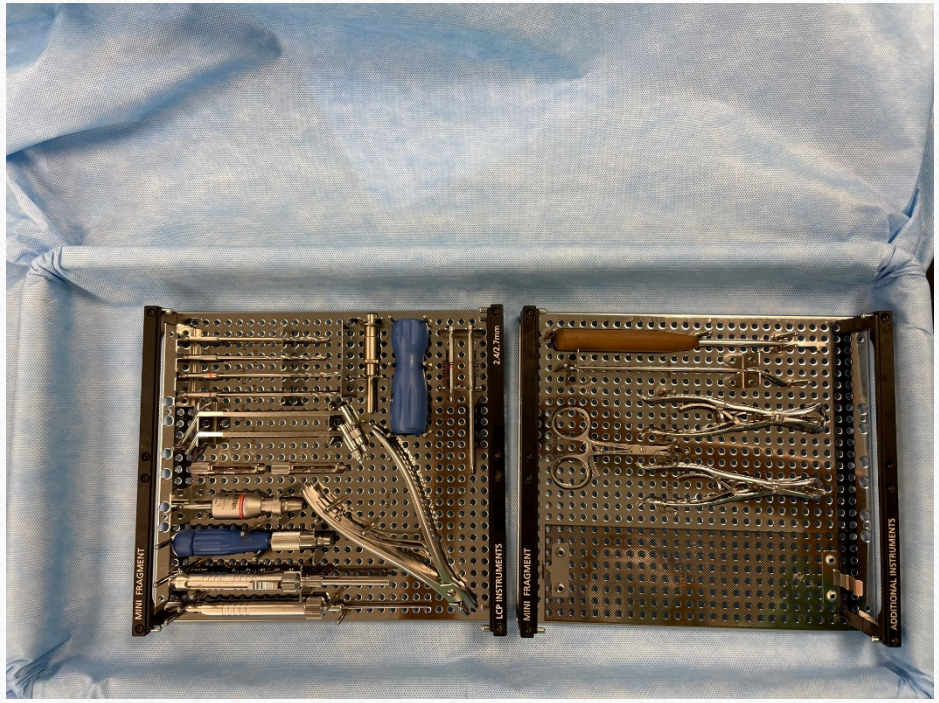
B. Improved Environment
Segregation of Facilities into Clean and Dirty Areas

B. Improved Environment
ISO Class 8 Cleanroom

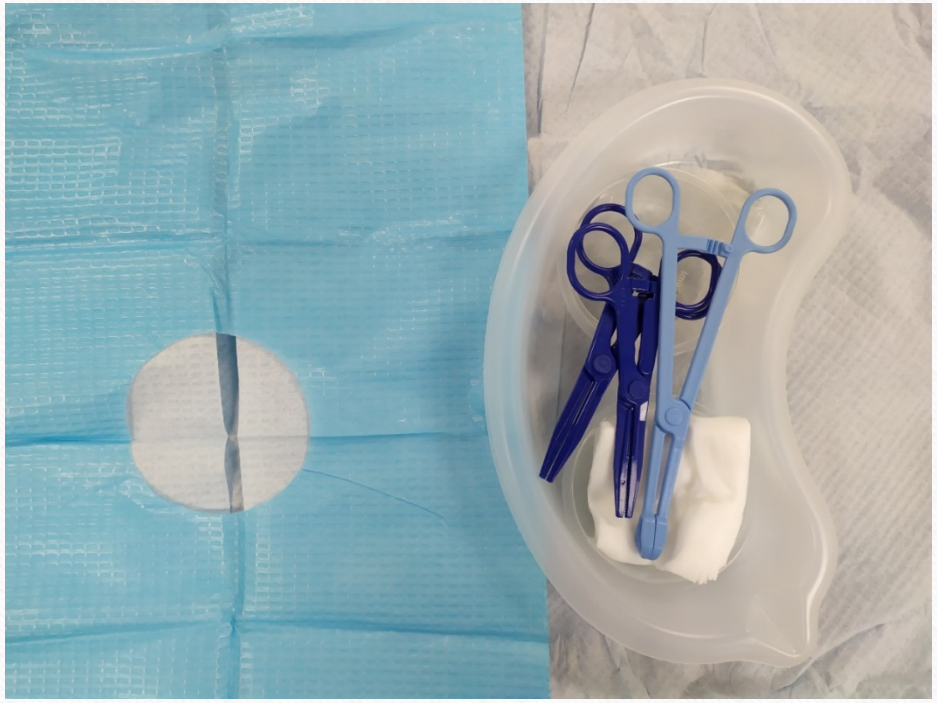
C. Upgraded Machines/Equipment
Water Treatment Systems

D. Up-to-Standard Materials
Disposable Wrappers



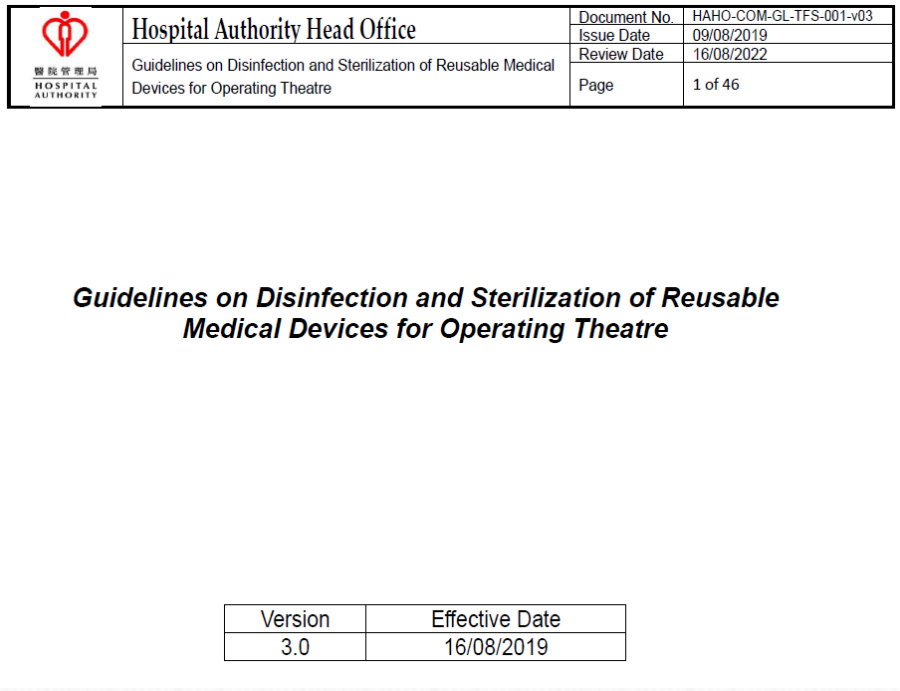


D. Up-to-Standard Materials
Disposable Drapes for OT



E. Methods/Processes

Revised Corporate Guidelines on Disinfection and Sterilization



Hospital Authority Head Office	Document No.	HAHO-COM-GL-TFS-001-v03
	Issue Date	09/08/2019
Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre	Review Date	16/08/2022
	Page	1 of 46

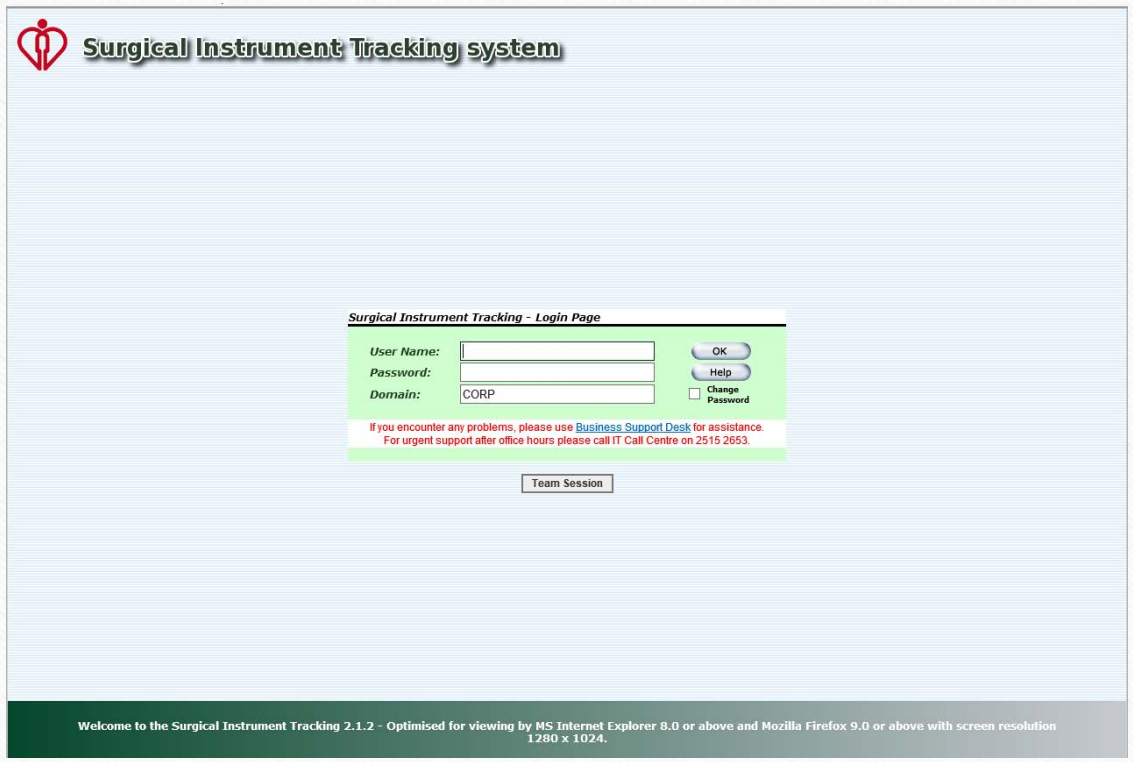
Guidelines on Disinfection and Sterilization of Reusable Medical Devices for Operating Theatre

Version	Effective Date
3.0	16/08/2019

- ISO 13485 Quality Management System
- ISO 17665 Steam Sterilization
- ISO 15883 Washer Disinfector
- ISO 14644 Cleanroom
- ISO 11607 Packaging Materials

E. Methods/Processes

Corporate-wide Instrument Tracking and Tracing System



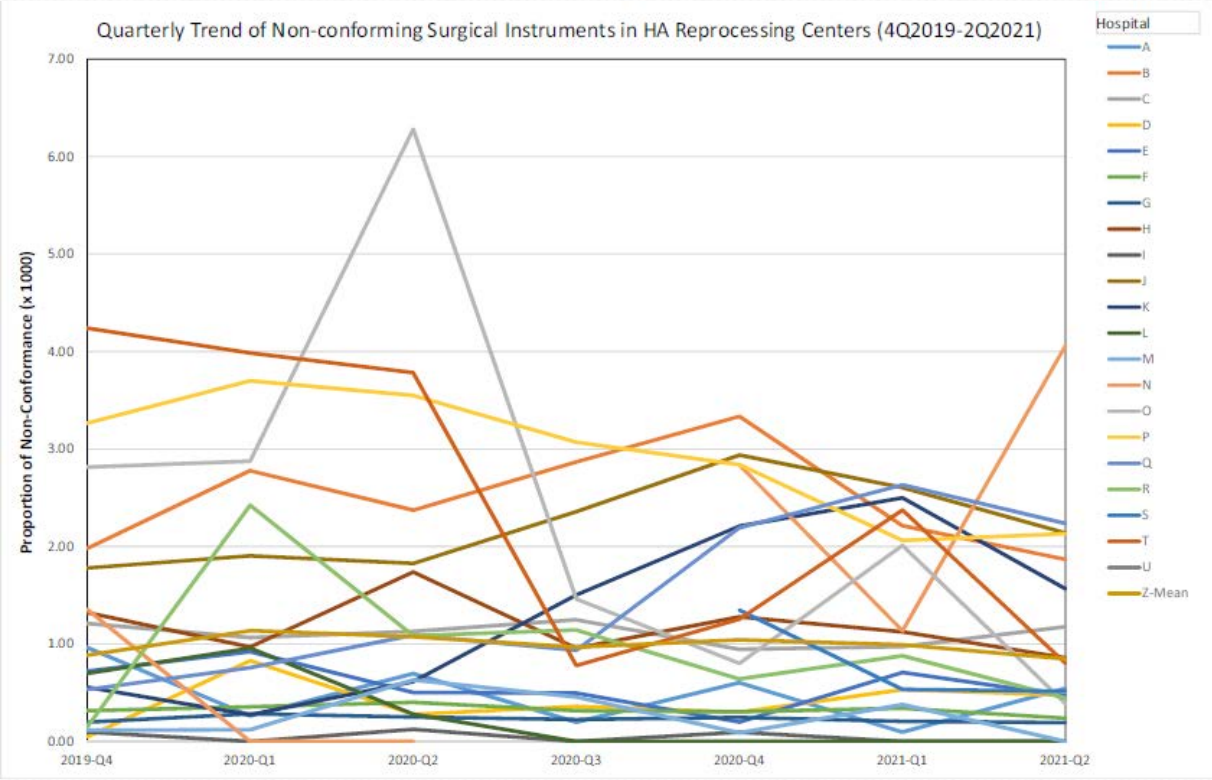
F. Measurements for Performance Benchmarking for Quality Improvement

	Non-conformity		Non-conformity
1	Wet Pack	7	Defect in External Chemical Indicator
2	Torn / Damaged Package	8	Missing Internal Chemical Indicator
3	Incorrect Set Label	9	Incorrect Instrument / Implant
4	Missing Warning Sheet	10	Dirty Instruments
5	Incorrect Packing	11	Damaged Instruments / Missing Parts
6	Incorrect Packing (Container)	12	Incorrect Assembly of Instruments

F. Measurements for Performance Benchmarking for Quality Improvement

	Non-conformity	Definition
1	Wet Pack	All package should be dry and free from water
		Instruments and instrument trays should be dry inside the package
2	Torn / Damaged Package	The package should be intact and clean

F. Measurements for Performance Benchmarking for Quality Improvement



Key Successful Factors

- Governance: Top-down and Bottom-up
- Train your people
- Guidelines, Guidelines and Guidelines

The Way Forward

- Governance structure
- Validation of cleaning, disinfection and sterilization processes
- Sterilization of flexible endoscopes

The Way Forward

- Obtain accreditation specifically for medical device reprocessing (such as ISO 13485)

INTERNATIONAL STANDARD

ISO 13485

Second edition
2003-07-15

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

Thanks for HAHO and Cluster Management Support