



Hospital Authority Convention 2014

Speed Presentation (SPP-P6.18)

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Implementation of a Quality Management System in Sterile Supply Service is Critical to Continuous Quality and Safety Improvement

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Introduction



Quality Management Systems for Medical Devices
ISO 13485:2003

Reference to Policy of Corporate

Quality Manual Policies and procedures

Decontamination Equipment

Management

- Washer Disinfectors
 ISO 15883
 HTM2030 (UK)
 - Sterilizers
 EN 285, ISO 17665
 HTM2010 (UK)
 - Other Equipment ISO 14937

The Facility

- Design HBN13 (UK)
- EnvironmentISO 14644

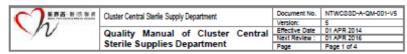
Risk Management
Training
Resources Monitoring
Auditing
Customer Focus
Tracking & Tracing of
Instruments





Quality Manual

- 1. Organization profile
- 2. Quality Policy and Objective
- Management Responsibility
- 4. Human Resources Management
- Material Management System
- 6. Product Standard
- 7. Risk Management, Measurement, analysis & Continue Quality Improvement
- 8. Document Control



Contents

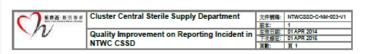
- 1.0 Introduction and Department Profile
 - 1.1 Introduction
 - 1.2 Department Profile
 - 1.21 Location
 - 1.22 Scope of Service
- 2.0 Quality Policy and Objective
- - Management Responsibility
 3.1 Management Commitment
 - 5.1 Management Commitme
 - 3.11 Mission
 - 3.2 Organization Chart
 - 3.3 Customer Focus
 - 3.31 External & internal communication
 - Nearly Missed Event, complaint, feedback management
 - 3.33 Regular meeting
 - 3.4 Management audit and review
 - 3.41 Audit and review on management system
 - 3.42 Review on SOP
 - 3.43 Review on instructions & guidelines
 - 3.44 Review on customer information & feedback
 - 3.45 Improvement & Recommendations
- 4.0 Human Resources Management
 - 4.1 Job description
 - 4.11 administrative staff
 - 4.12 frontline staff
 - 4.2 Duty Arrangement
 - 4.21 Duty Hours
 - 4.211 administrative Staff
 - 4.212 frontline staff
 - 4.22 Duty Request Guideline
 - 4.23 Overtime guideline
 - 4.3 Leave Arrangement







Nearly Missed Case Management



Quality Improvement on Reporting Incident in NTWC CSSD



All incidents should be reported thro' email within 48 hours .

•		
Severity	\rightarrow	Incident belongs to group 3 & 4 should report Ms. Li and Mr. Law verbally.
1. very low risk	→	Incident stopped before reach to end-user.
2. Low risk	→	Incident related to non-conformity
3. Moderate risk	→	Incident related to expensive instruments / potential complaint
4. High risk	\rightarrow	Incident may lead to delay in OT service/patient safety



westigation on the load

by Mr.Lee and Mr.Wan

Reported to Mr.Lee

Reported to Mr. Wan



Directed elated to OT



1. Review the system

2. Environmental control

Improvement strategies

Non-OT Related Incident





Set up Incident code



1. Incident Alert to ERMS

- 2. Incident Reminder(read and sign after Incident staff meeting)
- 3. Interview involved staff
- 4. Review the system
- 5. Other improvement strategies



- 1. Incident Report Statistics (3-monthy)
- 2. Incident Review Training (3-monthy all staff)
- 3. Incident Training Manual (New comers)



Incident Review meeting (6-monthy+ad-hoc)







was also found that foreign bodies

3/03/2011 P11003D T3017 Chan Siu Lee Tai Wong Ho Foreign Body and dirt was found 1. Root Cause

Tracking Set T3017

received call from the nurse of Theatre 8, who complained that

Perinmosting Saw Than clerk

in a saw & an air hose of Sterile Packers are careless.

Immediate Action-

hecking washing the air hose and checking the saw after Final Review (Date and

3/6/2011 by FOII Man Chan-





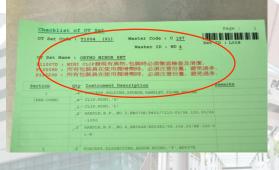
Incident Code:P12005D Finish Good Code: T1033

凹位必须微底清潔及"吹水",留意有沒有骨粉

所有包裝員及審核員須徹底檢查手術儀器是否潔淨。

包装医工作注意密度。









Key Performance Indicator

