FISPM Inc.
Fil-International Sterile Processing Management Inc.

INSTRUMENT TO PATIENT SAFETY

Best Practices in Sterilization Documentation

NOEL C. BASCO, JR.
European Certified-SPT, DGSV, SGSV, RN, CSSYB

October 24, 2019

Objectives:

At the end of the session, participants will be able to…

- ❑ Describe what is documentation
- ❑ Know the ways of documentation
- ❑ List down and identify the recommended sterilization documentation

Documentation

is essential in determining the reasons for sterilization process failures.

What is Documentation?

An act or an instance of supplying of documents or supporting references or records.

The orderly presentation, organization, and communication of recorded special knowledge to produce a historical record of changes in variables.

A legal form which can be used to furnish decisive evidence or information and serves as evidence of proof.

In CSSD….

Responsible for providing records of sterilization process.

Record history of the effectiveness of the process.

Provide legal document and proof of the outcome of the process.

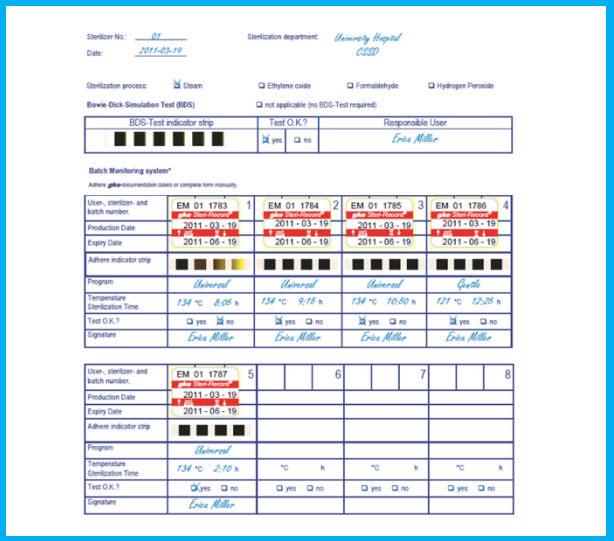
DOCUMENTARISTS

Not just a paperwork!

An essential element of Quality Control

Types of Documentation

Paper



Sterilizer No.: 01
Date: 2011-03-19
Sterilization department: University Hospital CSSD

Sterilization process: ☒ Steam ☐ Ethylene oxide ☐ Formaldehyde ☐ Hydrogen Peroxide

Bowie-Dick-Simulation Test (BDS) ☐ not applicable (no BDS-Test required)

BDS-Test indicator strip	Test O.K.?	Responsible User
■■■■■■	☒ yes ☐ no	Erika Müller

Batch Monitoring system*

Adhere *gke* documentation labels or complete form manually.

User-, sterilizer- and batch number.	EM 01 1783 1	EM 01 1784 2	EM 01 1785 3	EM 01 1786 4
Production Date	2011 - 03 - 19	2011 - 03 - 19	2011 - 03 - 19	2011 - 03 - 19
Expiry Date	2011 - 06 - 19	2011 - 06 - 19	2011 - 06 - 19	2011 - 06 - 19
Adhere indicator strip	■■■■■	■■■■■	■■■■■	■■■■■
Program	Universal	Universal	Universal	Gyn
Temperature Sterilization Time	134 °C 8:05 h	134 °C 9:15 h	134 °C 10:50 h	121 °C 12:25 h
Test O.K.?	☐ yes ☒ no	☒ yes ☐ no	☒ yes ☐ no	☒ yes ☐ no
Signature	Erika Müller	Erika Müller	Erika Müller	Erika Müller

User-, sterilizer- and batch number.	EM 01 1787 5	6	7	8
Production Date	2011 - 03 - 19			
Expiry Date	2011 - 06 - 19			
Adhere indicator strip	■■■■			
Program	Universal			
Temperature Sterilization Time	134 °C 2:10 h	°C h	°C h	°C h
Test O.K.?	☒ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no	☐ yes ☐ no
Signature	Erika Müller			

Electronic Log System

What Must Be Documented?

1. Installation, care and maintenance of sterilizers
2. Product identification and traceability
3. Medical device manufacturer's instruction-for-use (IFU)
4. Periodic product quality assurance testing routinely processed items
5. Implants
6. Recall of products processed within a healthcare facility
7. Medical device recalls, notifications or safety alerts

Installation, Care and Maintenance of Sterilizer

Documentation shall…

- ✓ Identify the equipment
- ✓ Establish a continuous history of all scheduled and unscheduled service

Sterilizer Qualification Testing

Using Biological Indicator Process Challenge Device (BI PCD)

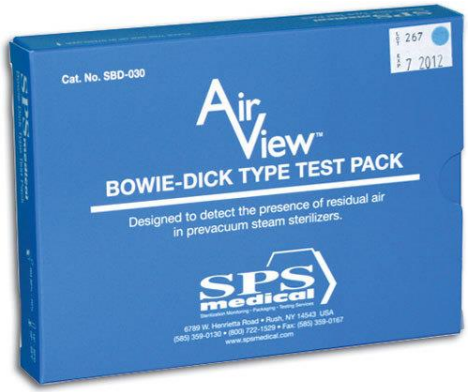
Perform Sterilizer Qualification Testing after:

- Sterilizer installation
- Sterilizer relocation
- Sterilizer malfunction
- Sterilizer major repairs
- Sterilization process failures

Sterilizer Qualification Testing

Run three consecutive cycles with BI PCD

Run three Bowie Dick test packs in three consecutive empty cycles
(for Dynamic-Air Removal Sterilizers)



Records shall contain the following:

1. date on which service was requested;
2. model and serial number of the sterilizer;
3. location of the equipment (healthcare facility identification, if applicable);
4. name of individual from healthcare facility who requested and authorized service;
5. reason for service request;
6. description of service performed (e.g., calibration, repair);

Records shall contain the following:

7. types and quantities of parts replaced;
8. name of the person who performed the service;
9. date the work was completed;
10. handwritten or electronic signature and title of person who acknowledged completion of the work; and
11. results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service.

DAVAO DOCTORS HOSPITAL
E. QUIRINO AVE., DAVAO CITY
PLAN PREVENTIVE MAINTENANCE AND CALIBRATION FOR THE YEAR 2019

ITEM	DESCRIPTION	QTY	YEAR 2019											
			JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
1	Steam Sterilizer MMM Selectomat PL6612-1 Serial No. B170242	1												

Legend :

Calibration Schedule

PM Schedule

Product Identification and traceability

Documentation shall…

- Identifies item or product processed
- Assists in proper stock rotation
- Ensures that cycle parameters been met
- Establishes accountability
- Assists with recalls

Every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted.

- *Record the sterilizer load identifier on the patient's chart*
- *Patient name on the load record*

Lot Control Numbers

Label the packs with:

1. Lot control identifier (sterilizer identification number or code)
2. Date of sterilization
3. Cycle number

Sterilizer Records

Information for each cycle includes:

- Lot number
- Contents of load
- Exposure time and temperature, if not on a recording chart
- Operator identification
- Results of BI testing
- Results of Bowie-Dick testing
- Results of CI in the PCD BI
- Any reports of inconclusive or nonresponsive CI's in the load

BI Documentation

- BI catalogue number
- BI Lot number
- Incubation time
- Result of test BI
- Result of control BI

Medical Device Manufacturer's Instruction-For-Use

- IFU shall be part of the Quality Control documentation.
- Ensures correct sterilization process is being used in the sterilization parameters for that process are correct.

AORN states for low temperature sterilization processes:

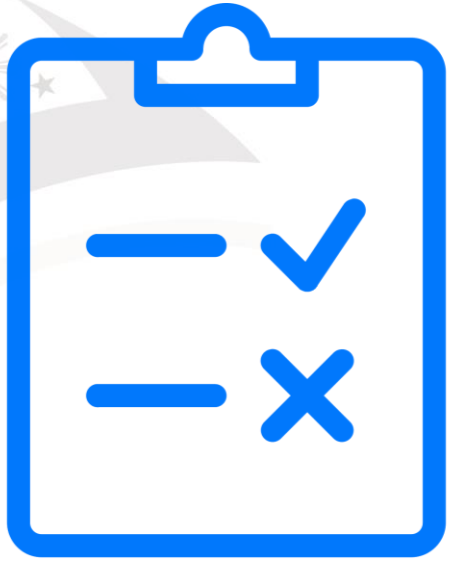
Follow the manufacturer's written instructions to determine if the item is compatible with EO and what the sterilization parameters are.

Obtain documentation from the device and sterilizer manufacturer of items that can and cannot be processed in hydrogen peroxide gas plasma. "Sterilization of devices to be processed in hydrogen peroxide gas plasma should be validated by the device manufacturer. Devices to be sterilized should comply with the sterilizer manufacturer's lumen claims relating to diameter and length of the device."

Periodic product quality assurance testing of routinely processed items

Product testing is recommended as part of a complete quality assurance program:

1. To ensure the effectiveness of the sterilization process.
2. To avoid wet packs.

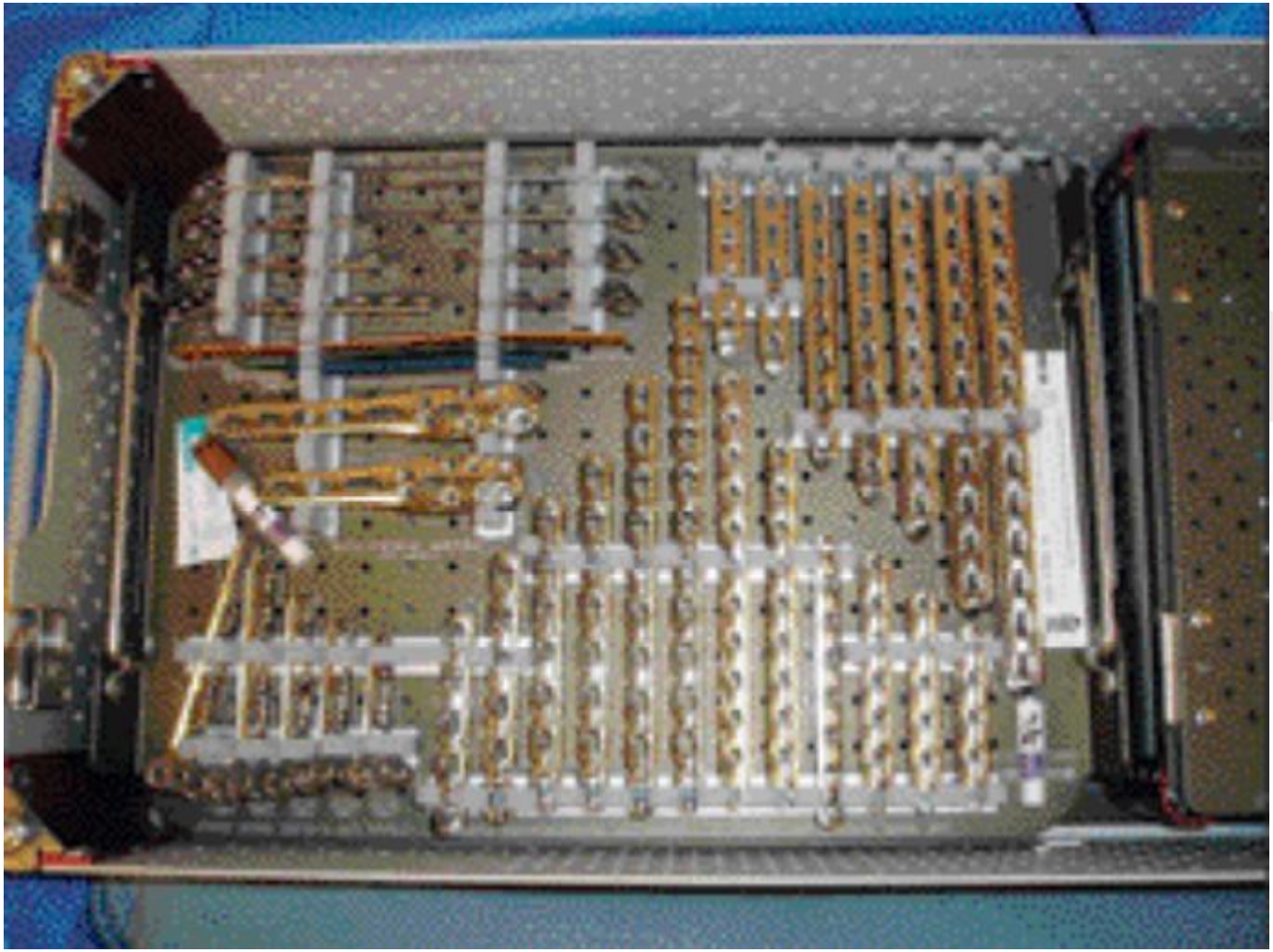


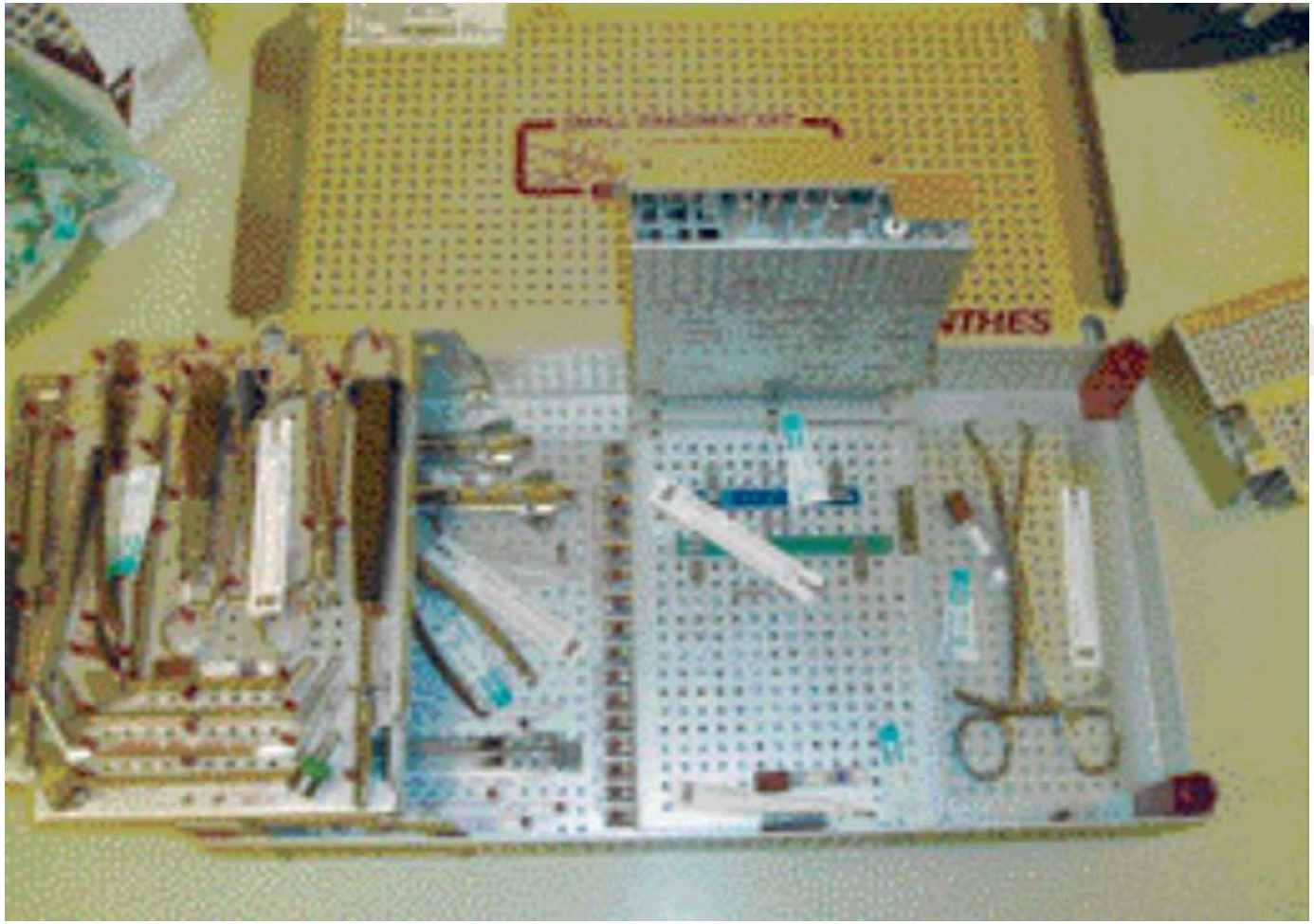
When to conduct?

➢ Periodically

And when:

- Major changes are made in packaging, wraps or load configuration
- Each loaner tray before it is put into routine use
- Medical device manufacturer's IFU are updated





Implants

Fully traceable to the patient whom it is used or implanted.

Each load containing implants should be quarantined until it is verified that BI testing has yielded negative results.

Flash sterilization should not be used for implantable devices

Implantable Devices Load Record

Date	Description of implants	Dept.	Time sterilized (specify AM/PM)	Sterilizer #	Load #	Date/time BI in incubator	Date/time and BI result	Early release?	Date/time released to OR	Released by (full name)

Implantable Devices Load Record

DECONTAMINATION										STERILIZATION		STERILIZATION			STORAGE								
Series #	Date Received	Time Received	Instruments' General Description	Supplier	Name of Representative	Contact #	Implantable? (Y/N)	Accredited? (Y/N)	Decontamination Staff	Date of Sterilization	Time of Sterilization	Batch #	BI Result (Neg/Pos)	Sterilization Staff	Date Released to OR	Time Released to OR	Receiving OR Staff	Patients Name	Surgeon	Date of Procedure	Time of Procedure	Storage Staff	Remarks

Pre-Mature Release of Implants

Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.

Emergency situations should be defined in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management.

Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ **SHIFT:** _____ **TIME:** _____ **AM PM**

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

_____

_____

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

_____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ **AM PM DATE:** _____

REASON PREMATURE RELEASE WAS NEEDED: _____

_____

_____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE/TRAY?

_____

_____

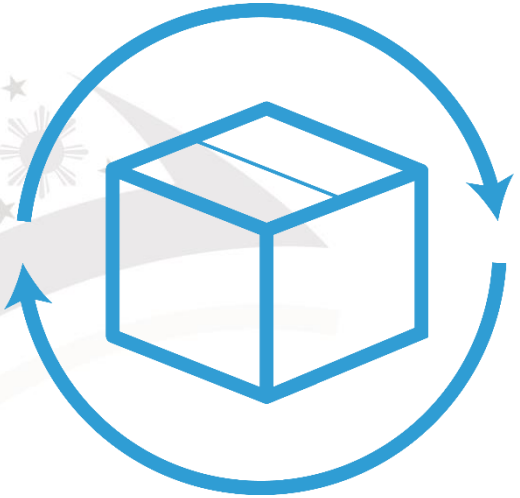
_____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ **RETURNED TO CENTRAL SERVICE ON:** _____

Product Recall

Must have written policies and procedures.



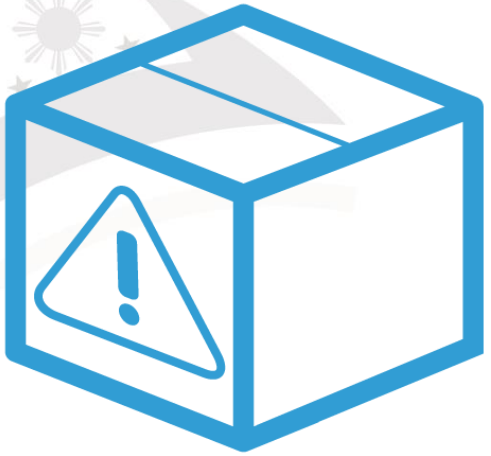
Objective:

To expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as quarantine of the sterilizer, notification of physicians and affected clinical departments, and surveillance of patients.

As soon as the BI is positive, recall all loads processed since the last negative BI.

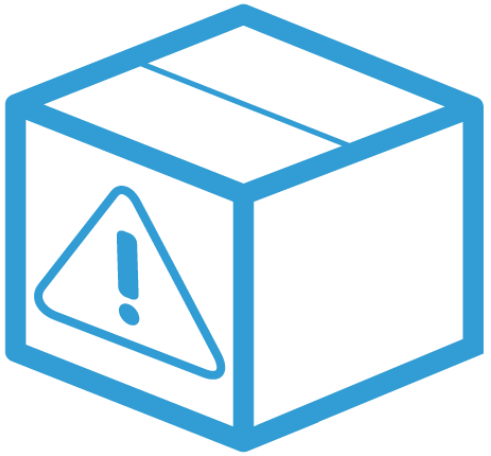
Medical device recalls, notifications or safety alerts

A healthcare facility also needs to respond to medical device recalls, notifications or alerts that inform healthcare professionals of a risk of substantial harm from a medical device in commercial use.



Medical device recalls, notifications or safety alerts

A healthcare facility also needs to respond to medical device recalls, notifications or alerts that inform healthcare professionals of a risk of substantial harm from a medical device in commercial use.



References:

Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2017

Recommended Practices for Sterilization in the Perioperative Practice Setting. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc: 2012

Young, M (2007). *Documentation: It's Not Just a Paperwork*. Managing Infection Control. Workhorse Publishing.

Larson, D (2012). *The Right Documentation! An Examination of Sterilization Record Keeping.* Healthcare Purchasing News. KSR Publishing. April 2012


IDOCS
Instrument Documentation System

Instrument Documentation System

D2D

Instruments accountability from Delivery to Disposal (D2D)

Traceability

Minimize lost instruments and avert retained surgical items.

Efficiency

Increase work output and prevent errors.

Customer Satisfaction

Minimize complaints.

Automated Report Generation

Repairs
Routine Maintenance
Inventory Management
Sets Optimization
Instrument Utilization
Sterilization Cycles
Cycle Failures
Batch Monitoring
Load Records

FISPM Inc.
Fil-International Sterile Processing Management Inc.

INSTRUMENT TO PATIENT SAFETY

Thank you!