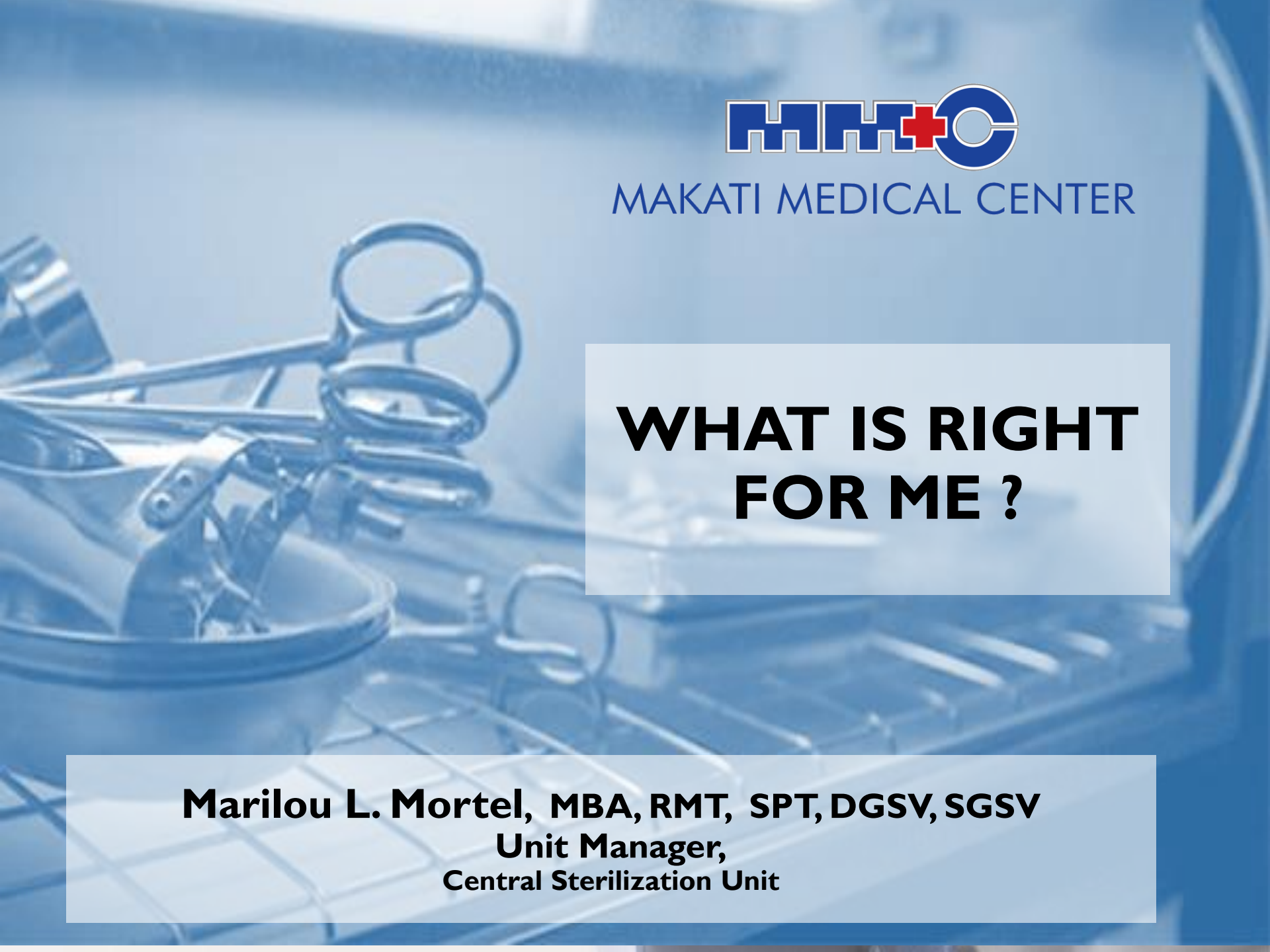


MAKATI MEDICAL CENTER

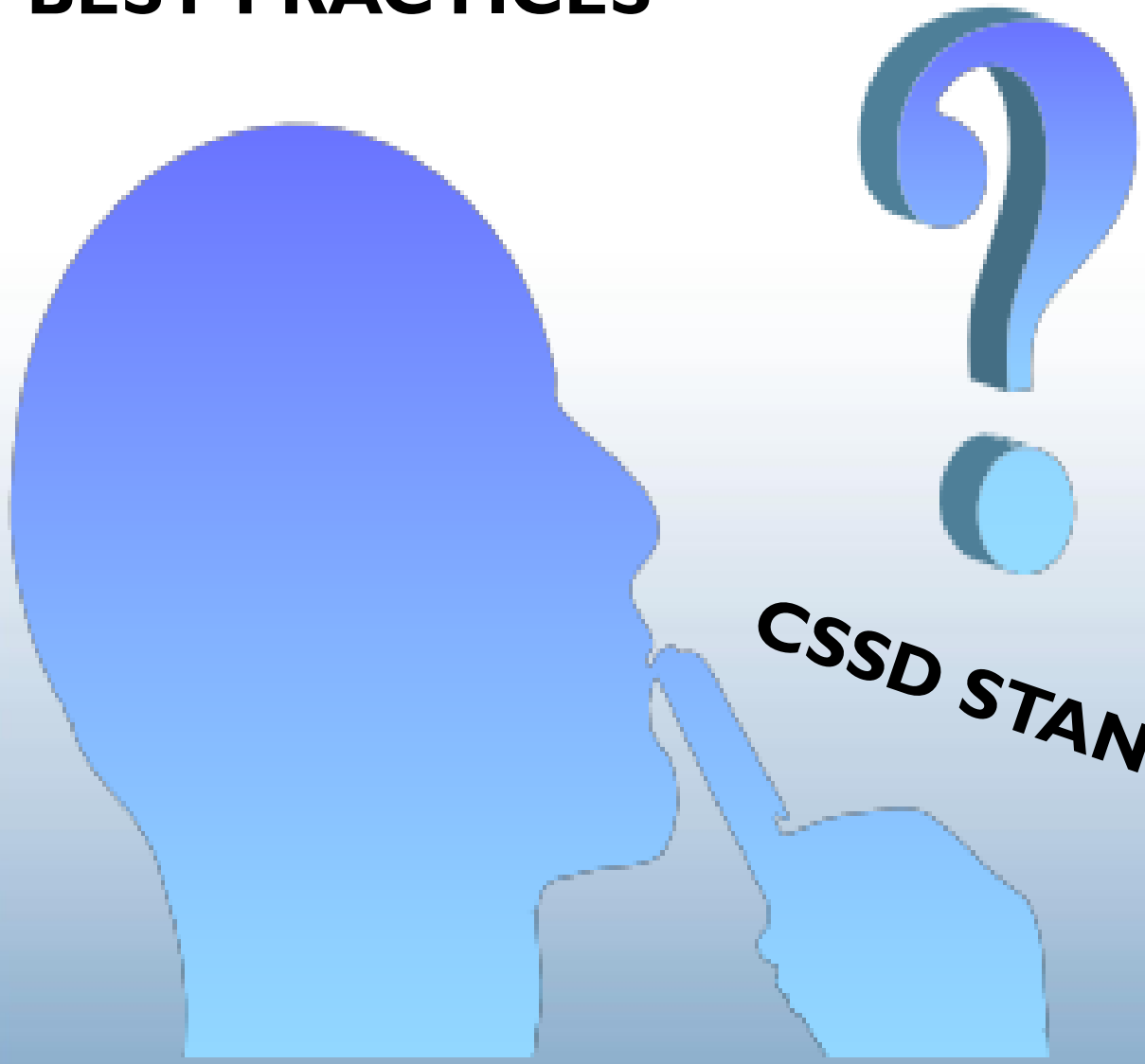
WHAT IS RIGHT FOR ME ?

Marilou L. Mortel, MBA, RMT, SPT, DGSV, SGSV
Unit Manager,
Central Sterilization Unit

OBJECTIVES

- To know and discuss the regulatory and professional standard
- To show the process of Best Practices in the Philippines (Makati Medical Center)
- To discuss about Dr. Spaulding Classification
- To present the importance of Staff safety

BEST PRACTICES



CSSD STANDARDS ?

FDA - *regulates manufacture of all medical devices and requires premarket of new medical devices. It is also regulates the sterilants and HLD's used to process critical and semi-critical devices.*

EPA *is responsible for minimizing greenhouse gases and toxic emissions, regulating the reuse of solid wastes, controlling indoor air pollution, and developing and enforcing pesticides regulations.*

All EPA approved products must contain the following label information:

- *Product ingredients*
- *Directions for use*
- *Product precautions and warnings*
- *Directions for storage and disposal*
- *EPA registration number*
- *Expiration date (if applicable)*

REGULATORY AND PROFESSIONAL STANDARD

CDC - *works to promote health of life by preventing and controlling disease, injury and disability, and by responding to health emergencies.*

Although CDC are not considered regulatory, other agencies rely heavily on them and review healthcare facilities for compliance, manufacturer to provide IFU that the healthcare facility must follow.

CSSD *users are responsible for:*

- *Confirming they have the facilities and equipment to execute the instructions.*
- *The verification of manufacturer's instruction and ensuring the instructions are followed.*

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

OSHA – *primary role and responsibility is to protect workers from occupationally caused illnesses and injuries.*

Note:

Non-compliance with the standard, such as not following the guidelines for transportation of contaminated instruments or not complying with the PPE requirements carry heavy fines.

OSHA®
Occupational Safety and Health Administration

AAMI – *Association for the Advancement of Medical Instrumentation*

Voluntary guidelines representing a consensus of AAMI members that are intended for use by healthcare facilities and manufacturers to help ensure that medical instrumentation is safe for patient use.

2011-TJC-refencing AAMI/ST79 during facility survey.

AAMI – *documents have been approved by the* **ANSI** - *American National Standard Institute*.

ANSI – *is the sole US representative to the* **ISO** - *International Standards Organization.*

AORN - *The Association of periOperative Registered Nurses*
a professional organization consisting of perioperative nurses and others who are dedicated to providing optimal care to the surgical patient.
AORN - *has a devoted topics directly affecting the CSSD.*
These includes on Cleaning, Disinfection, Packaging, Endoscope reprocessing and Sterilization.

ISO – *The International Standard Organization*

A non-profitable organization with a network of National Standards Institute representing 163 countries.. International Standards give-state-of-the-art specifications for the products, services, and good practice, helping to make industry more efficient and more effective.

THE JOINT COMMISSION – *is a private independent, non-profit organization that develops standards for healthcare facilities.*

TJC *personnel evaluate healthcare organizations and program in the US by conducting on-site surveys at least every 3 years.*

CSSD personnel must understand and cooperate with their facility's procedures to comply with TJC.

Know the following:

Mission and consistently comply with all safety standards.

NFPA – *National Fire Protection Association - is an organization that works to reduce the burden of fire and other hazards around the world.*

NFPA - *is important to CSSD personnel because of the fire safety standards used for the buildings in which they work.*

USP- NF – *United States Pharmacopoeia -*

National Formulary creates and revised standards for the purity of medicine, drug substances and dietary supplements.

For CSSD standards are set for packaging, labelling, bacteriology purity, pH and ,mineral content.

This is very important to CSSD personnel who works with purified water or sterilizing water for irrigation.

WHO – *The World Health Organization – is an agency of United Nations that was established in 1984 to further international cooperation in improving health conditions.*

WHO *staff members coordinate international efforts to monitor outbreaks of Infectious Diseases, such as SARS, malaria, AIDS and CJD.*

This agency provides a central cleaning house for research services and international standards. Agencies, such as CDC, base many standards on the research and direction provided by WHO.

For example:

Processing items contaminated with CJD are from WHO.

World Health Organization

Society of Gastroenterology Nurses and Associates, Inc.

SGNA – *Society of Gastroenterology Nurses and Associates – is non-profit organization of nurses and associates dedicated to the safe and effective practice of gastroenterology and endoscopy nursing.*

SGNA - *collects information and establishes standards and guidelines relating to the processing of flexible endoscopes.*

CSA – *Canadian Standard Association - is a nonprofit organization that develops standards for industry, government and healthcare for all Canadian providences.*

CSA *has developed many standards for the processing of surgical instrumentation.*

CANADIAN STANDARDS ASSOCIATION

EUROPEAN COMMITTEE FOR STANDARDIZATION – CEN – *sets the standards for Europe in much the same way that AAMI sets for the US. The 33 member countries have adopted CEN standards exclusively. US companies that sell products for instruments processing in EU must follow CEN standards for the products sold in member countries.*

BEST PRACTICES IN CSSD

CULTURE OF CARE

JOINT COMMISSION INTERNATIONAL
QUALITY APPROVAL

MAKATI MEDICAL CENTER - STRUCTURAL DESIGN

CULTURE OF CARE

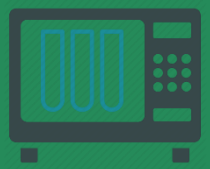
SOILED

CLEAN

STERILE

STORAGE AREA

Instrument flow is **SOILED** to **CLEAN**



Instrument Flow and **Personnel Flow** are well considered to enhance efficiency and sustain a high-level sterilization and reliable output

CULTURE OF CARE

Quality Disinfection and Sterilization

Reprocessing of Surgical Instrumentation

Transport

Start of Instrument Flow

Cleaning/Disinfecting

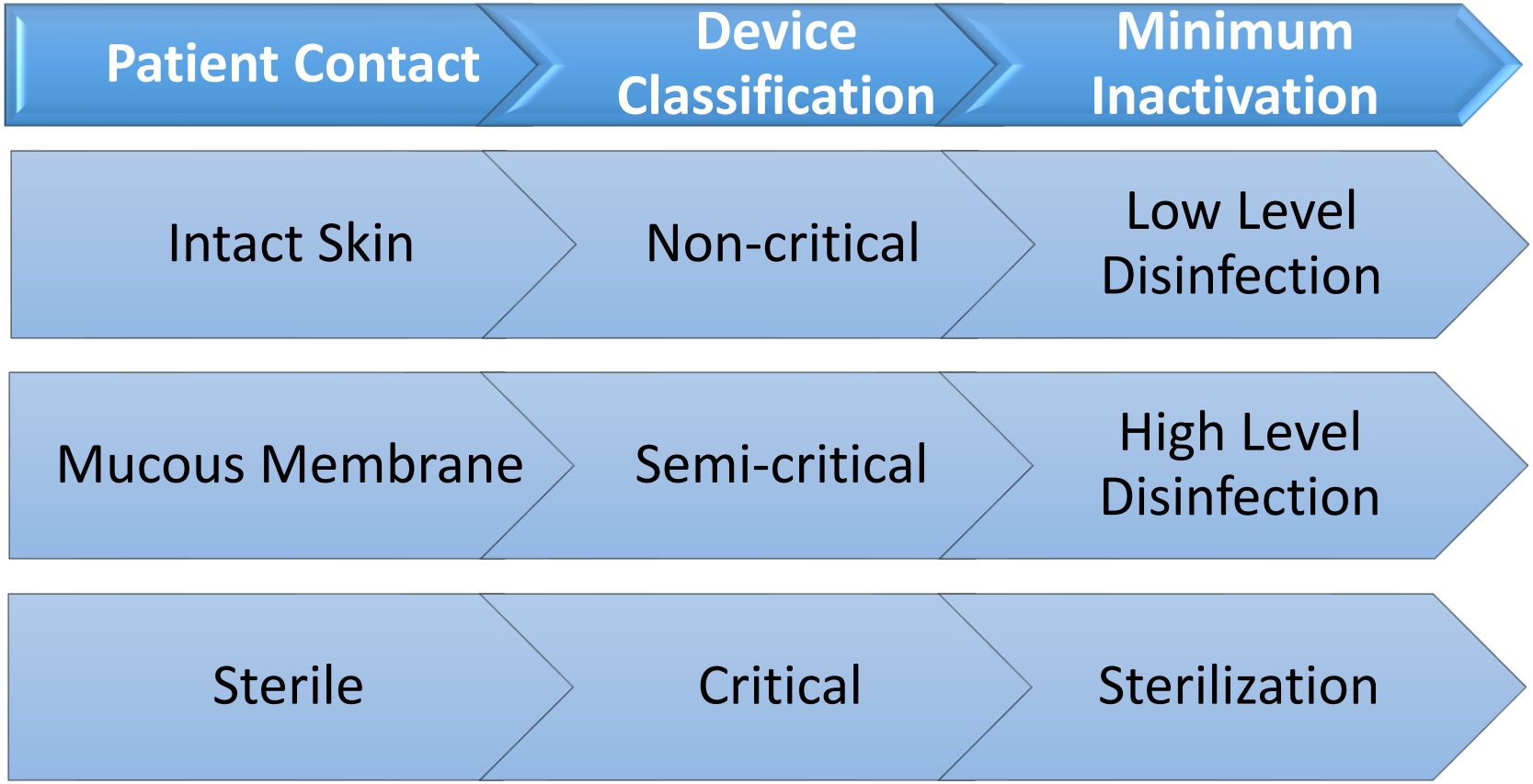
Storage

Quality Assurance

Sterilization

Packaging

SPAULDING CLASSIFICATION



Best Practice in **DECONTAMINATION**

CULTURE OF CARE

Mode of Cleaning

- Ultrasonic Decontamination
- *Thorough* Manual Cleaning
- Mechanical (Washer Disinfectors)

Facility

- Negative Pressure Room
- Monitored Temperature
- Maintained Humidity(up to 70%)
- Eye Wash Station

Cleaning Agents

- Water (Reverse Osmosis)
- Enzymatic Cleaner
- High Level Disinfectant (HDL)

PACKAGING

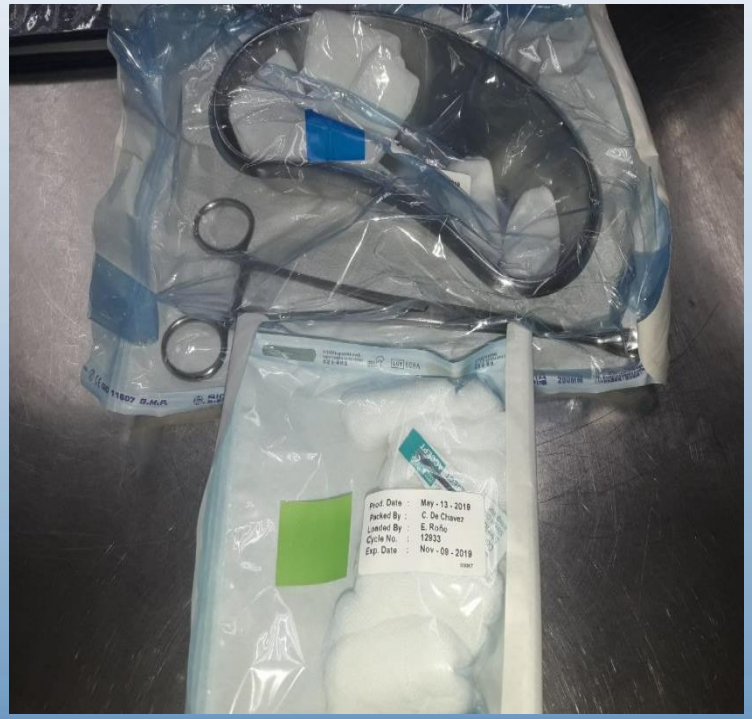
CULTURE OF CARE

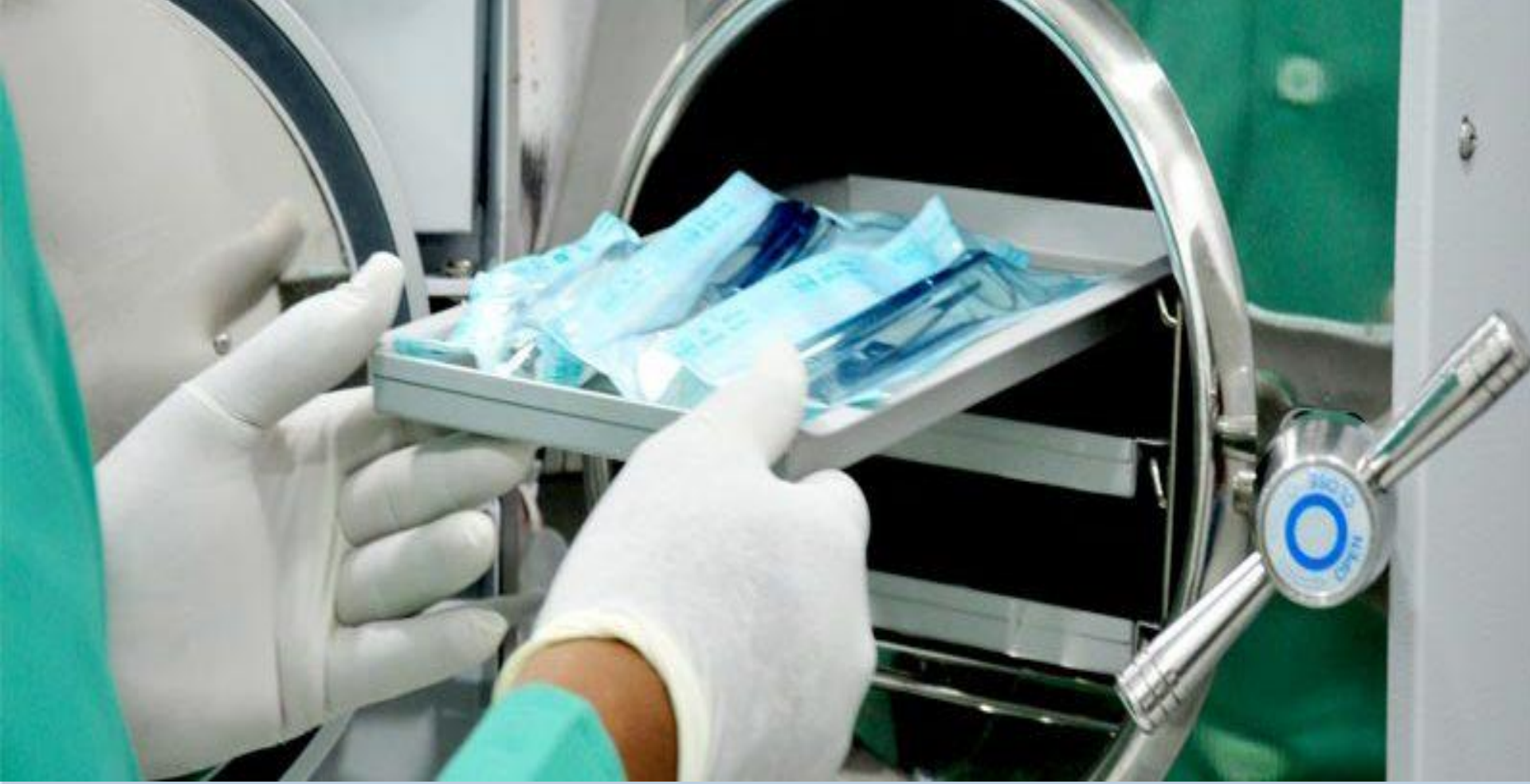
WITHOUT PACKAGING , STERILE ITEM IS USELESS

CULTURE OF CARE

CONTAINERIZED SYSTEM

POUCHES





Sterilization

a process that destroys or eliminates all forms of microbial life.

METHODS IN MAKATI MED	
Steam Sterilization	**Plasma Sterilization**

Best Practice in **STERILITY ASSURANCE PROCESS**

Physical + *Chemical* + *Biological* = **Sterility Assurance**

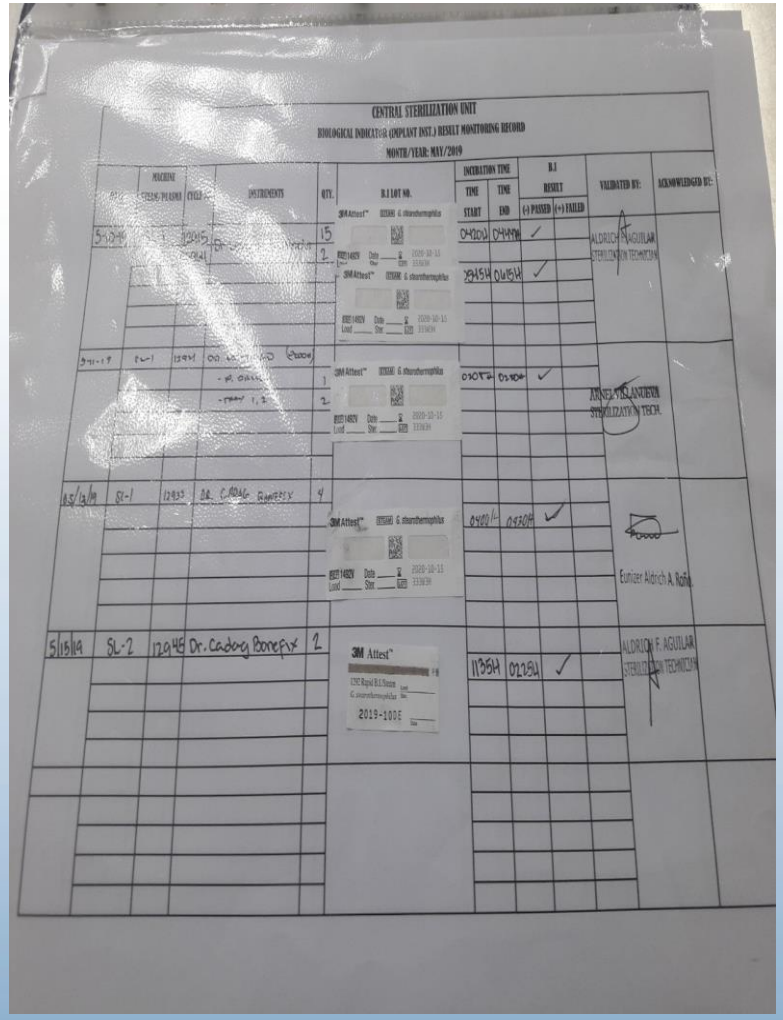
Cycle Time, Pressure, Temperature

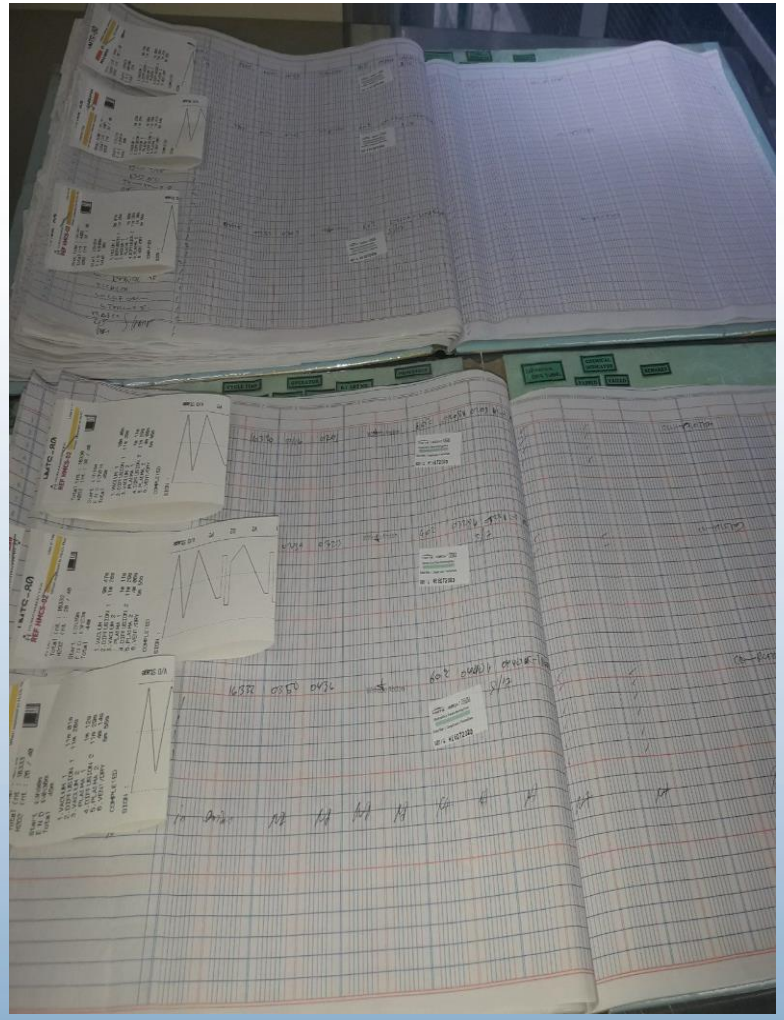
Heat or chemical sensitive inks that change color when germicidal-related

Bacillus spores that directly measure sterilization

DOCUMENTATION

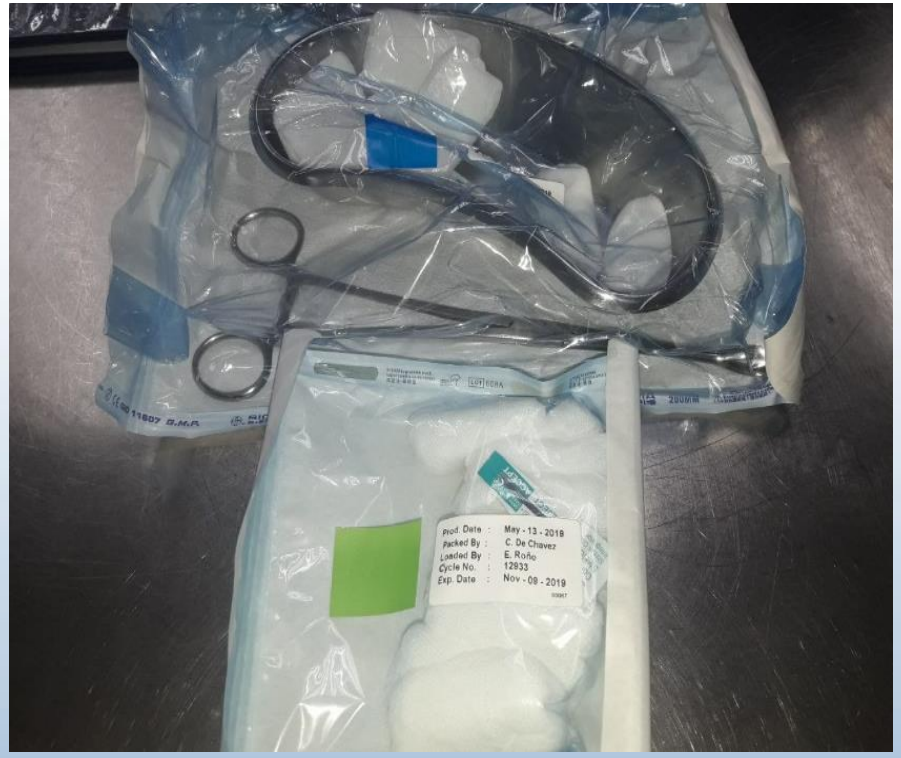
CULTURE OF CARE





Monitoring Logbooks and Print outs

CHEMICAL AND BIOLOGICAL INDICATOR



Chemical

Biological

Commitment to Education and Research

CULTURE OF CARE

Staff must be properly trained to ensure their safety and the safety of the patients they serve.

Orientation includes:

- ❑ Regulations
- ❑ Reference manuals
- ❑ Safety Information

Refresher courses are given to all CSU and OR staff every year.

CARE FOR STAFF SAFETY AND CONSIDERATION

CULTURE OF CARE

Implement Culture of Safety

Uphold Occupational Health and Exposure

Patient-Care Devices: Cleaning & Maintenance

Antimicrobial Resistance & Infection Control, 2018

Thank You