Monitoring your decontamination and reprocessing cycle

1er Journee National sur la Sterilisation

La Societe Marocaine de Sterilisation

Maroc 2011

Ahmed Ghatwary/SteriGMS/Pharcomedic

Index

1-Cleaning step, the most important part of the decontamination cycle.

2-SBS, its importance and the international norms.

3-Monitroing your sterilization process and assuring SAL

4-Conclusion

Cost of hospital infections

- USA recent research:
- Deaths due to hospital infection:

  77,000 p.a
- Infected patients:

  2,200,000 p.a
- Average excess hospitalization:

  4 days
- Average cost per day:

  500 $
- Total cost of extra care:

  4,500 Million US $

Sterility - How do you know ?

- Those responsible for sterilization need to know if their sterilization process was effective.
- Secure sterilization relies on the correct performance of the apparatus, the operator and packaging materials

The chain is as strong as its weakest link

Cleaning Processes

- Instrument cleaning is the first and arguably the most important step in the decontamination process.

- Microscopic quantities of blood, skin, mucous etc. left on the instruments by an ineffective washing process can seriously compromise the overall sterility of the instruments.

How to monitor our cleaning processes???

Manual Cleaning

- We have to monitor the cleaning efficacy of the operator.
- By the end of the day we don't get the same results as the beginning of the day.
- Some devices are more complex than others, thus require better cleaning.
- Sometimes combined with Ultrasonic cleaning
- Always dismantle instruments when possible
- Separate sinks washing and rinsing.
- Use Distilled water.
- Protein testing is a way to monitor your manual cleaning, according to HTM0105 it's a daily test
- Inspection before sterilization

Washer disinfector

- Always better than manual cleaning
- Complying with the ISO 15883.
- Protocol in accordance with the 15883
- Use the right PCD (process challenge device)
- Use good source of water for rinse.
- Use one of the soil tests mentioned in the ISO 15883-5
- Documentation of the results
- Validating according to IQ, OQ and PQ.

EN ISO 15883

- Part 1: General requirements, terms and definitions and tests

- Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

- Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

- Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

- Part 5: Test soils and methods for demonstrating cleaning efficacy (Technical Specification)

Materials used in sterilization

What is an SBS?

- SBS refers to Sterile barrier system
- Allows sterilization of the item
- Provides physical protection and microbial barrier
- Maintain sterility over certain period of time
- Allows aseptic presentation at point of use

1- Pouches and Reels

1-One side medical grade paper and the other side film

2-The paper has class 1 indicators to ensure that the pack has been processed

3-The sealing machine must be validated to make sure that there is no tracks in the seal (Seal check)

4-It must be rightly packed, stored to be stored for and intended certain of time.

Requirements of International Norms

- Paper has to be not less than 60gsm (Micro tears)
- Medical grade paper acting as a microbial barrier(long and short fibres)
- Some people use 70gsm paper
- Film preferable to be over 60gsm
- Printing requirements (class 1 indicator, etc)
- No visible damage to the film

2-Crepe paper

- It is a medical grade paper
- It is used to wrap the items to be sterilized then to be loaded in the sterilizer.
- It has no indicator
- Manufactured from Long fibers to ensure penetration of steam and then acts as microbial barrier
- Must Be double packed and the right way of packing must be used (tortuous path)

Difference in wrapping materials

	Crepe Paper	SMS	Non woven
Most common basis weight	60 gsm	45 gsm	57 gsm
Composition	100% cellulose	100% PP	Mix
Advantages	No drying problems	Strength	Drapeability and strength
Disadvantages	Weak in wet conditions	Drying problems	None
Pricing	Lowest	Highest	High

Wrapping paper

- Micro tears can appear in case we don't use the right gsm.
- Double wrap has become a must.
- Appearance of interfoliage products for double wrapping.
- Claims against the ordinary SMS use for the time being.
- Right method of wrapping is a must to guarantee sterility.

3-Tape

- It is used to close the crepe paper
- It has an indicator of class 1 printed to make sure that the load has entered the sterilizer.
- It can not be considered as a validation of the steam sterilization cycle.

Tape Class 1 indicator

- EN ISO 11140:2009
- Class 1 indicator is an indicator that changes its color at a certain temperature and time.
- It must have good adhesion.
- Clear color change
- Resistant to temperature

4-Tyvek

- One side Tyvek and the other film.
- The Tyvek side has printed on it indicators for plasma.
- Tyvek was manufactured mainly to replace paper for plasma sterilization
- Tyvek is the brand name, Material is LPDE
- Dupont is the only manufacturer
- Only the GSM can be different and coating

Tyvek

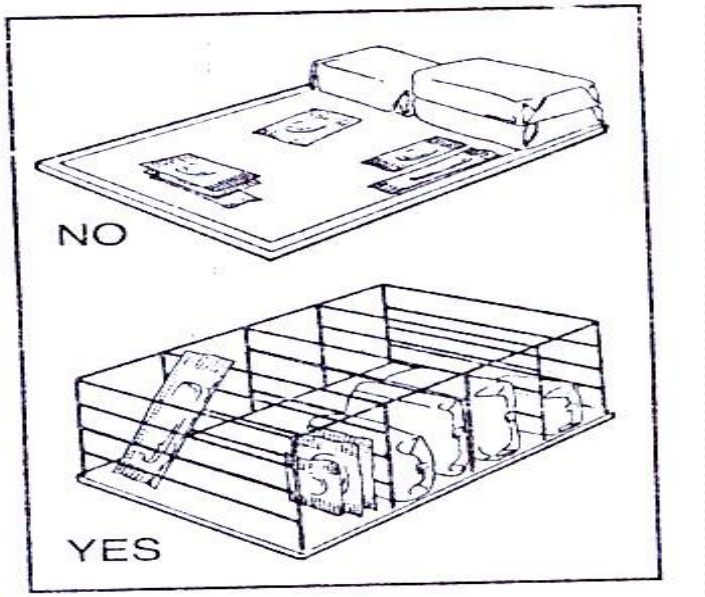
- Reason is CELLULOSTIC
- It can be used for ETO and steam under certain conditions
- Higher strength and tear resistance.
- It can be used for sharp items and heavy loads.

5-Self Seal Pouch

- One side paper one side film.
- Instead of heat sealing, self sealing
- Various sizes
- Class 1 indicator printed
- Used a lot in dentistry
- Can be used as a backup in case sealing machine is broken
- Follow the instructions of use for sealing the double face.

The operator

- Washing..Washing…Washing!!!!
- Washing is monitored through the soil test.
- Packaging using the right method.
- Loading in the apparatus using the right method.



GHATWARY GMS MEDICAL SUPPLY

International Norms

- “The product shall not be printed on any surface which is designed to come into direct contact with the items to be packaged”
- “Information required to be printed on the surface of reels and pouches is specified”
- “Materials shall not be leaching and odourless under specified conditions of use”
- “Materials shall be free of holes cracks “
- Materials shall have a basis weight which is consistent”

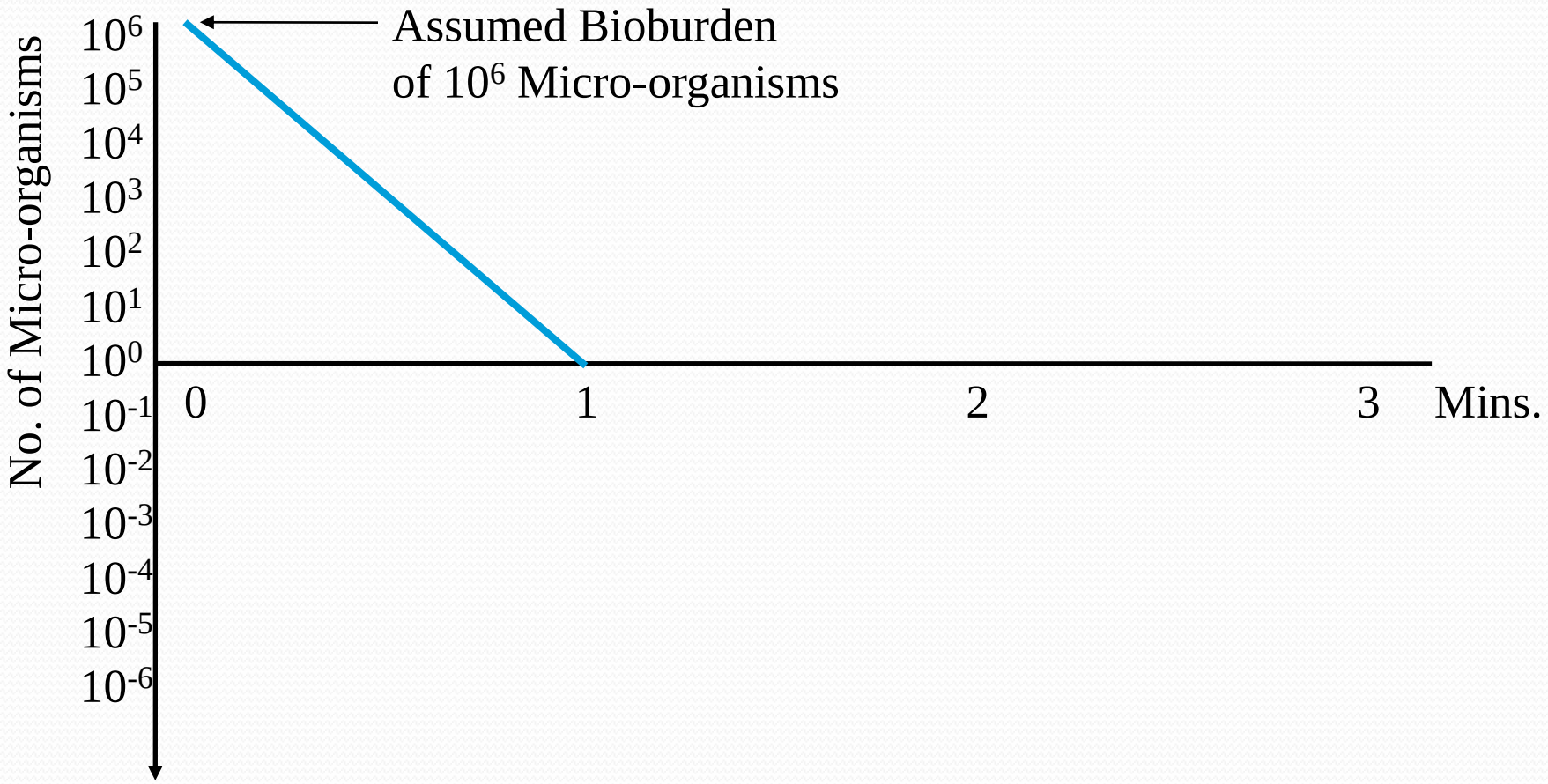
Monitoring your sterilization

Sterility Assurance

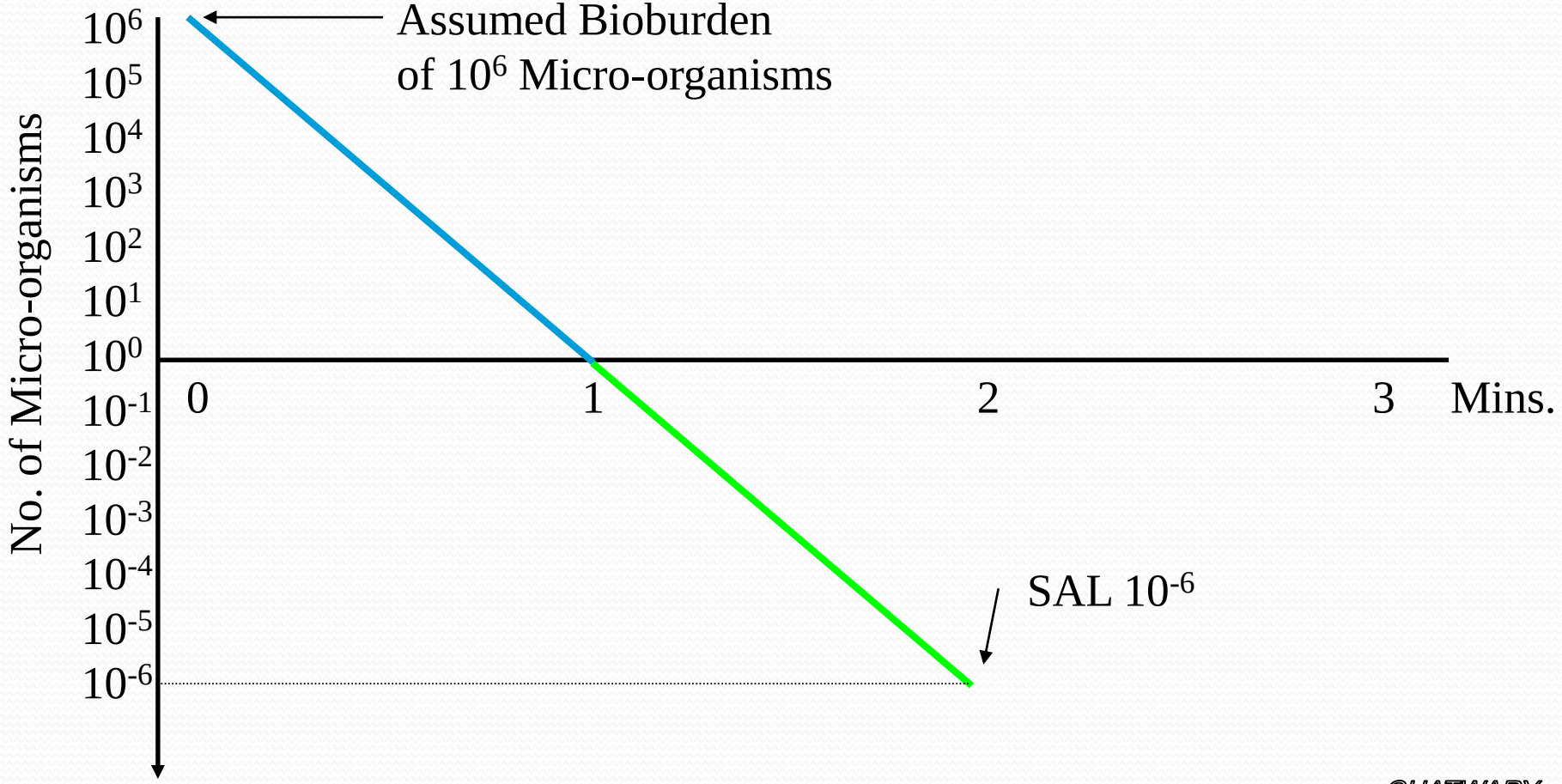
The Sterility Assurance Level, or SAL, is a measure of the confidence in the attainment of sterility

- a probability of 1 unsterile load in 1,000,000

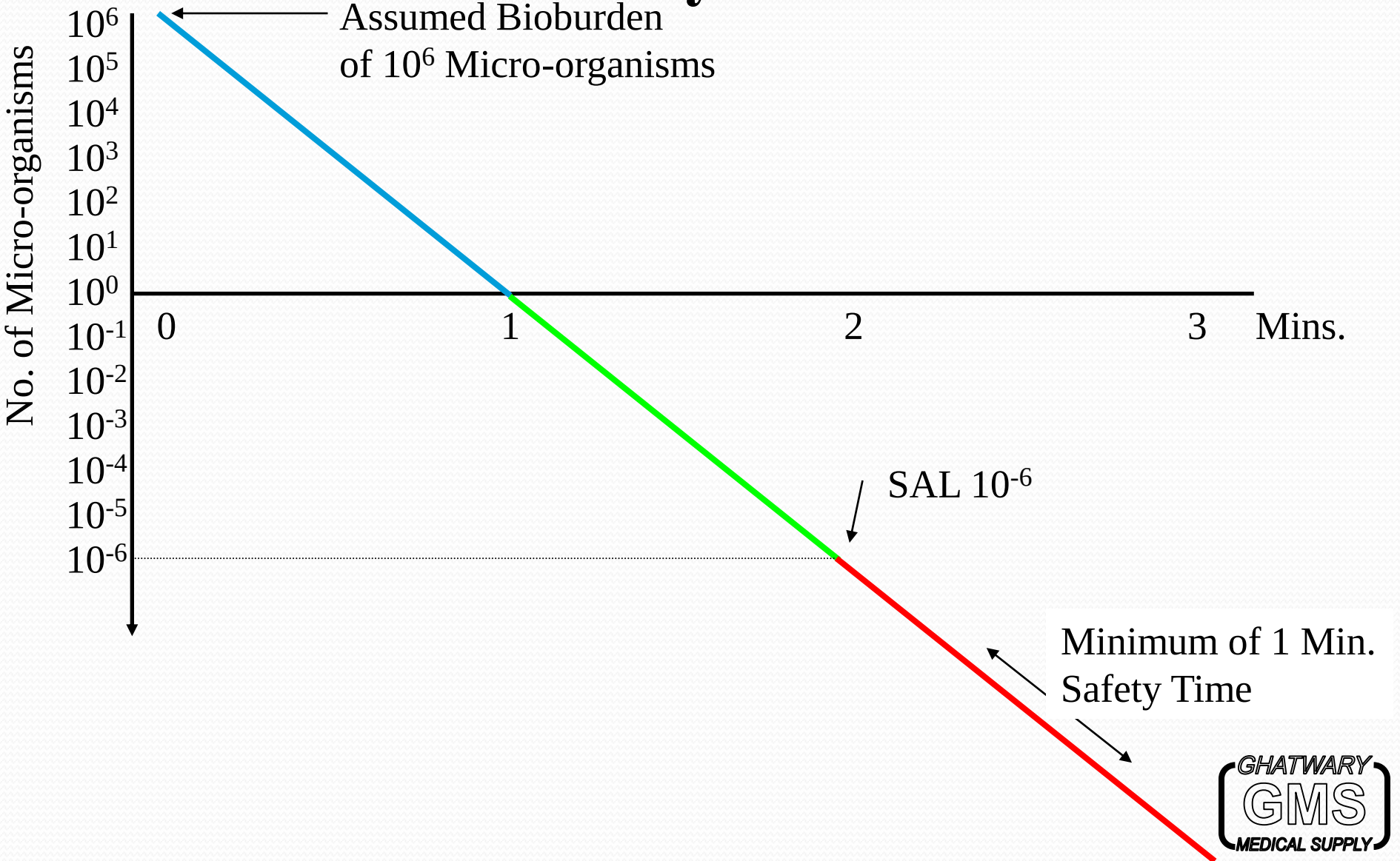
First Minute of Cycle at 134ºC



Second Minute of Cycle at 134ºC



‘Safety Time’


No. of Micro-organisms
10^6
10^5
10^4
10^3
10^2
10^1
10^0
10^{-1}
10^{-2}
10^{-3}
10^{-4}
10^{-5}
10^{-6}
Assumed Bioburden
of 10^6 Micro-organisms
0
1
2
3
Mins.
SAL 10^{-6}
Minimum of 1 Min.
Safety Time

ISO11140 Classifications

Class 1: Process indicators

Class 2: Indicators for use in specific tests

Class 3: Single parameter indicators

Class 4: Multi-parameter indicators

Class 5: Integrating indicators

Class 6: Emulating indicators

Class 4

Class 4 – Multi Parameter Indicator

- Must react to 2 or more parameters
- For steam the tolerances are;

time +0%, - 25%

temperature +0, -2C

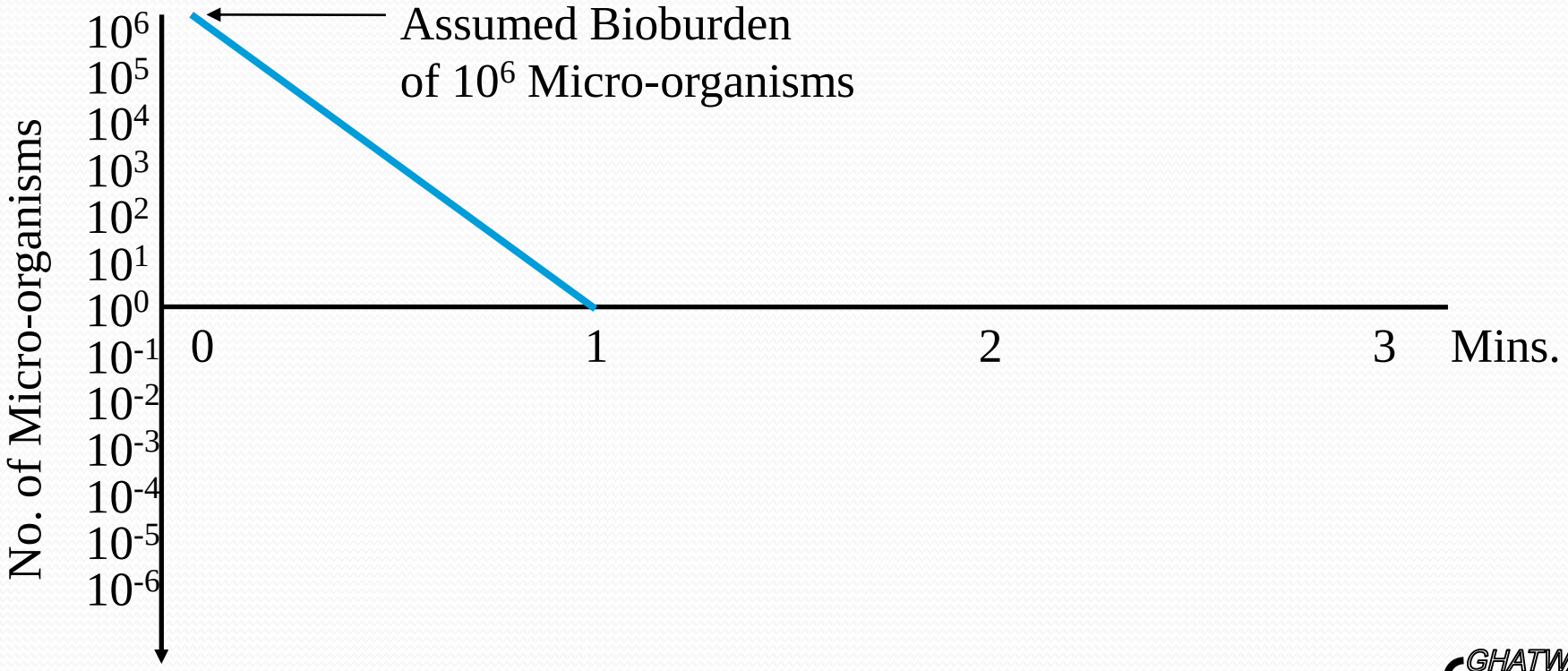
One calibration of Class 4 indicator is found around the world.

ISO11140 - Class 5 - Integrating Indicators

- Also known as ‘chemical biological’ indicators
- Must react to all critical parameters of a given process
- Follow the death curve of a given spore population, e.g. B. stearothermophilius in steam as per ISO 11138 part 3

GHATWARY GMS MEDICAL SUPPLY

Class 5 indicators



Class 6

A Class 6 indicator would prove that all parameters of a given process were present as per values stated on the indicator.

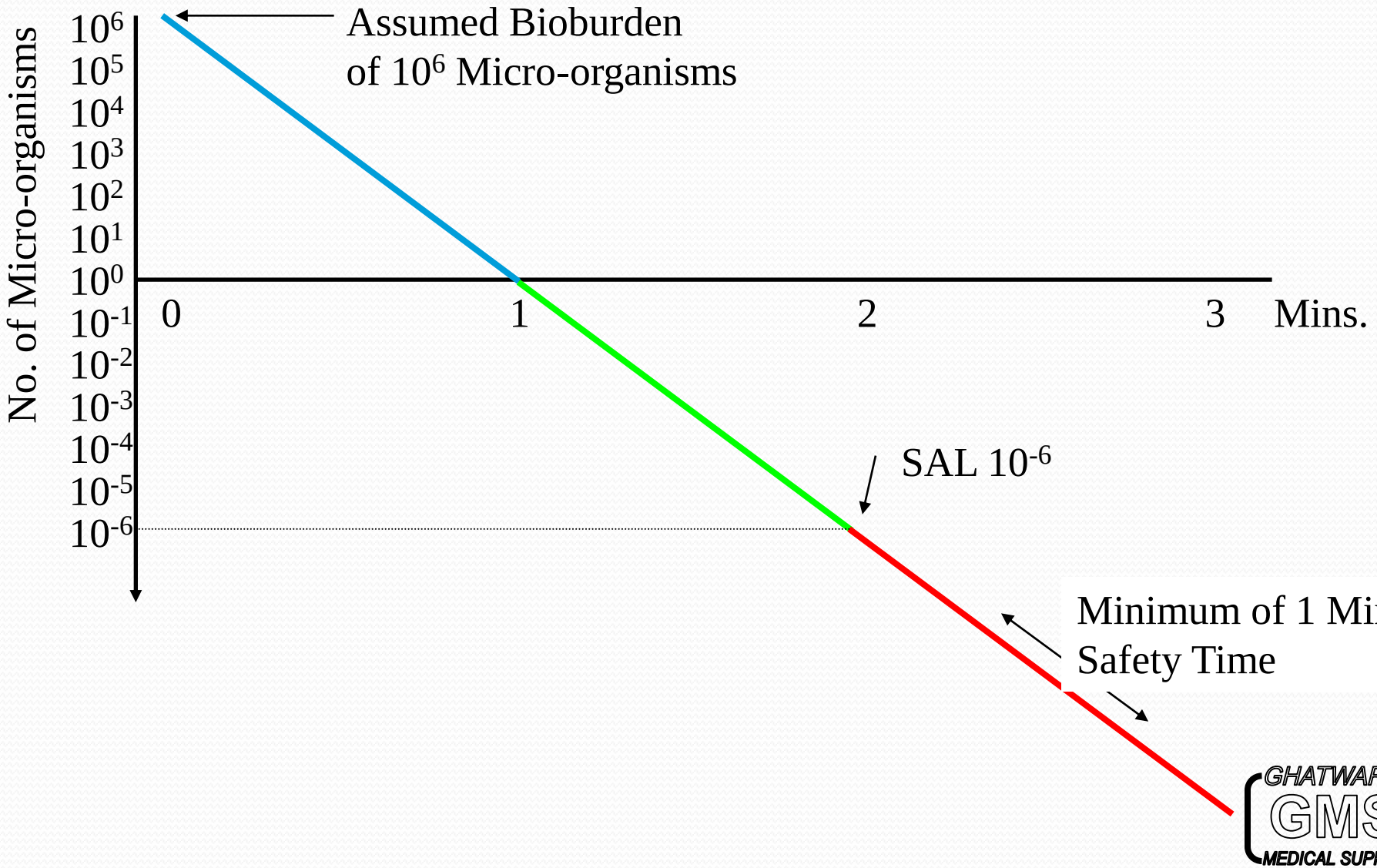
Monitoring all 3 critical parameters of Time, Temperature and Steam

Cycle emulating

E.g. 134 C for 3.5 , 4, 7, 9, or 18 min
121 C for 20 min

GHATWARY GMS MEDICAL SUPPLY

Class 6



GHATWARY GMS MEDICAL SUPPLY

Load Control Vs In pack monitoring

Load control

- Assurance of the load.
- Physical evidence inspected and retained within the CSSD before the load is released
- Indicators are generally classified (class 2)and therefore no method of determining specific characteristics.

In pack monitoring

- Assurance of the pack or tray.
- Physical evidence is inspected by the end user and retained at point of use.
- Indicators classified according to their performance and characteristics.

Other factors to consider

- Loading of the sterilizer:
- Overloading
- incorrect loading
- Packaging
- Packaging materials

GHATWARY GMS MEDICAL SUPPLY

Surgical Safety Checklist

World Health Organization | Patient Safe

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?

- ☐ Yes

Is the site marked?

- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?

- ☐ Yes

Is the pulse oximeter on the patient and functioning?

- ☐ Yes

Does the patient have a:

Known allergy?

- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?

- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?

- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:

- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:

- ☐ Are there any patient-specific concerns?

To Nursing Team:

- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?

- ☐ Yes
- ☐ Not applicable

Before patient leaves operating roo

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:

- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to b addressed

To Surgeon, Anaesthetist and Nurse:

- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

Team Work

Alignment

Thank You