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Review Article

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"Process control methods of sterilization vapor pressure"

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Keywords

hospital environment,
Sterilization,
physical,
chemical and
biologicals.

Abstract

The healthcare or hospital environment may be contaminated with a variety of microorganisms capable of producing disease in humans.
Although this situation is not decisive in itself, yes it is a very infectious risk important, since these microorganisms can initiate an infection if a potentially infectious amount is in communication with a gateway or a person susceptible host.
Therefore, we must ensure that all items direct care receive appropriate treatment to minimize or reduce that risk.
Sterilization processes should be routinely subjected to controls demuestren its effectiveness. For a product to be classified as sterile, it should ensure that all stages of the process were carried out correctly and that the sterilization process is validated.
For monitoring the sterilization process indicators are used: the sterilization indicators are equipment or reagents that target or validate certify that the process carried out properly. The indicators are classified as: physical, chemical and biologicals.

Introduction

The results of the sterilization cycle are not verifiable by inspection or testing of materials, as such products lose their status sterile. This difficulty requires one hand to validate the sterilization process globally according to the different controls and secondly to credit and store certification. The effectiveness of the sterilization process. For a product to be classified as sterile, it should ensure that all stages of the process were carried out correctly and that the sterilization process is validated.

Sterilization processes should be routinely subjected to controls demonstrate their effectiveness.

Said control system in which each part relates to the whole, harmoniously and accurate, is designed so that the sum total, and not each piece separately, assures us that our approach was successful and that therefore our sterilization processes are safe and effective, must control the process in each step and this should be recorded therefore, include identification records and control charge and discharge, contributing to product traceability.

In order to properly control the sterilization processes it is necessary to know in depth:

• What is the way of work equipment,
• its current state,
• failures they may have,
• how to control
• their areas of tolerance.

A control system must meet the following objectives:

• Identify each material.
• To record through a chemical control of the process was done.
• Set an acceptable operating point.
• previously detect equipment failures.

For monitoring the sterilization process indicators are used: the sterilization indicators are equipment or reagents that target or validate certify that the process carried out properly. The indicators are classified as: physical, chemical and biological.

include control input used at each stage in the process control, the raw material (gauze, paper, cotton, etc.), biological monitors, chemical indicators, etc. When the control result is satisfactory, it will be passed to the next stage.

	Tipos de controles	Detectan
Controles de esterilización	Indicadores físicos	Funcionamiento mecánico
	Indicadores químicos	Tº; vapor; tiempo de exposición
	Indicadores microbiológicos	Destrucción de microorganismos y esporas

Physical indicators

They are incorporated as elements of sterilant, such as thermometers, pressure gauges (barometers), timers, sensors load, valves and registration systems parameters, among others. To visualize if the team has reached the required parameters for the process.

Today, many teams have a microprocessor that prints the characteristics of the process at all stages, however, these monitors may contain errors or may not reflect what actually happens with the process. This is especially true because of the existence of other factors affecting the sterilization, such as the size of the load and the presence of organic matter not detected by physical monitors.

If the load abnormality seen in these parameters may not be considered sterile, so even be useful are not an effective means of testing sterilization. They must be made every day and at all levels, at the beginning, during and at the end of the cycle.

Physical monitors are useful, but not sufficient sterilization indicators. They must also be calibrated periodically to ensure the information they provide.

Frequency of use:

• In each sterilization cycle.

Temperature:

• Through own temperature sensors and other external apparatus (thermocouples, etc.). temperature chamber and the interior of the packets are recorded.

Pressure:

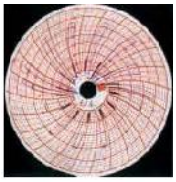
• Through gauges, pressure gauges or pressure sensors to be calibrated periodically.

Weather:

• According own clock periodically calibrated equipment.

At the end of the cycle, check with paper records that could deliver the equipment, compliance with the parameters required values for total sterilization cycle.

Such records must be filed with the rest of the documentation process.



1. image on the left: Diagram Digital Print

2. Right-Image: Diagram chart

Chemical indicators

There are internal and external chemical controls:

- external chemical Controls: are placed on the outside of the package or the elements
sterilize and to verify if the material was subjected to a sterilization cycle or not.

- internal chemical Controls: are placed inside the package. In cycles moist heat and steam temperature indicators are used.

Both types must be placed in each package can be multiparameter integrators that integrate several physical parameters and indicating that the sterilization requirements (T °, humidity.) Have been met within the package / container / bag, so it is regarded as valid (sterile).

Package internal monitoring confirms that reached sufficient sterilization conditions.

Must be examined each control when you open the package and always before using the instrument of a package or container valuing the indicator reaction.

The contents of packages whose chemical control has not veered properly or those where there is doubt, be considered as non-sterile.

There are also chemical controls for autoclaves operating as the Bowie and Dick, which it consists of placing a sheet control in the center of a standard textile package for detect penetration of the steam inside the package.

Frequency of use:

• In each cycle and / or package.

• Chemical indicators used for each process must meet the following conditions:

- Printed with non-toxic tape.

- stable over time.

- Easy reading and interpretation.

- allowing the reproducibility of the process.

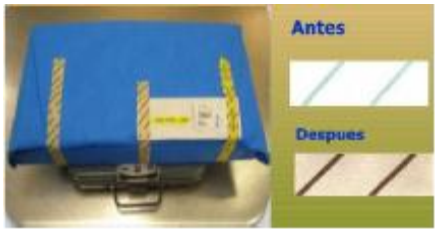
Process indicators

Tipo de indicador:	Controla:
Clase I: Indicadores de proceso.	Distinguen entre unidades procesadas y no procesadas.
Clase II: Indicadores para usar en pruebas específicas.	Test de Bowie-Dick
Clase III: Indicadores de un parámetro	Responden a un parámetro. Por ej., temperatura.
Clase IV: Indicadores de múltiples parámetros.	Responden a más de un parámetro crítico, como temperatura y tiempo.
Clase V: Indicadores integradores	Responden a todos los parámetros críticos y es ajustado a la respuesta de los indicadores biológicos.
Clase VI: Indicadores emuladores	Responden a todos los parámetros críticos y es ajustado a los de un ciclo conocido.

Tape - Class I

-They are adhesive tapes impregnated with thermochemical ink that changes color when exposed to a certain temperature. They are intended to prove that the article was exposed to the sterilization process and distinguish between processed and unprocessed items. These devices are based on chemical reactions and are sensitive to parameters of the different methods of sterilization (saturated steam, temperature and time).

They are in the form of strips of paper printed with ink and other nontoxic reagents that change color when the requirements for the process are met. Importantly, these products veer if a key element such as the temperature, and not necessarily the three elements mentioned both are true.



Bowie Dick test - Class II

It is a method to assess the effectiveness of the vacuum system of the autoclave pre-vacuum, whose purpose is to demonstrate the absence of air or other non-condensable gases in the sterilization chamber that can prevent the rapid and uniform penetration of steam inside load.

The test packet will consist of cloths or pure cotton towels, folded so that finally reach the extent of 22 x 30 x 25 cm and weighing approximately 6.5 kg. In the center of the package a test sheet will be placed Bowie Dick and everything will have its corresponding wrapper.

This package is placed in the bottom of the chamber near the door and horizontally (parallel to the sheet sterilizer base).

cycle at 134º C with exposure time between 3.5 to 4 minutes is performed.

At the end of the cycle the package is removed and the results will be interpreted:

• correct test: The indicator will be shifted to another key evenly and in its entirety.

• Incorrect test: It is manifested by a more subdued color as indicated by the manufacturer or by the appearance of spots or areas of different color or color density.

Currently there are packages that replace the factory mentioned earlier.

• Key issues If the test indicated an incorrect sterilization (positive) it must be repeated. If this is confirmed, you discontinue operation of the equipment and seek assistance maintenance (checking trap, solenoids and vacuum pump). After the review, we will take the test to confirm its operation.

Single indicator parameter - Class III

It is an indicator only parameter. In this case, only it indicates that the package was exposed to a certain temperature, according to the Association for the Advancement of Medical Instrumentation.
It is performed for checking the temperature during the sterilization process.
It is noteworthy that at present, there are already new indicators and these are entering into disuse in our midst.

Multiparameter Indicator - Class IV

• It is a type of indicator of multiple minimum parameters (time and temperature) of the sterilization process.

• It consists of a strip of paper impregnated with thermochromic ink which changes color when exposed to was the minimum necessary conditions of the method.

Integrating indicator - Class V

• They are designated to respond to all critical process parameters autoclave (temperature, time, steam quality) within a specified range of the sterilization cycle indicators.

• They shall be used within each packet as an internal indicator.

Simulators indicators verification cycles - Class VI

• They are also known as indicators designated simulation to react to all critical parameters within a specified range of sterilization cycles also specific.

• They work when 95% of the specific cycle has been completed.

• And reading performance is similar to that of integrator type indicators, Class V.

Biological Indicators

Biological controls are currently the only means available to confirm the sterilization of an article or to determine the effectiveness of the sterilization process.
Frequency of use:

• Moist heat: one per week.

Each biological indicator must specify:

• amount of spores
• Lot No.
• Expiration date
• value D

Biological controls must meet national or international standards.

Control Location:

• For camera control: dispose in the most inaccessible to the sterilizing agent, into a syringe and jacketed places.

• To control packages: provide control in the center of a package to be placed in the most inaccessible place the sterilizing agent.

Biological referents:

• Moist heat: Bacillus stearothermophilus is a Gram-positive bacterium bacillus shaped falls within the phylum Firmicutes. It is a thermophilic bacterium widely distributed in soil, hot springs and ocean sediments and causes decomposition of foodstuffs
.
Biological indicators are preparations containing a sufficient charge of high strength microorganisms (Bacillus stearothermophilus) sterilization and whose destruction, when subjected to a given cycle, it indicates that it has been well developed. They are designed so that the reading and interpretation is easy and quick to confirm the presence or absence of viable microorganisms after sterilization process.

These indicators should be introduced into the interior, and at the midpoint of the larger and heavier load packages. different controls in the different cycles of each team should be used.

In 1996, Rutala classified biological indicators: first, second and third generation, according to the order growth, speed and speed of appearance of results.

1st Generation: Before 1970, the paper strips B. stearothermophilus inoculated with spores were placed in envelopes, and after completion of sterilization, is passed aseptically, to a bacteriological laboratory broth, and incubated for 7 days before reading. the sterilization failure was checked, visually observing the turbidity produced by the growth of microorganisms in the broth. Disadvantages of this system include the need for a long incubation time and the need to transfer, mechanically, spore strips to the culture broth, which could cause a possible contamination.

2nd Generation: In the 70s, biological indicators on separate systems was introduced, where the spore strip and the average, were within an individual plastic vial. After sterilization, the glass vial inside broke, allowing the medium to come into contact with the spore strip. Also a pH indicator (bromocresol purple), which changes color when exposed to acid derivatives originating in the growth of the organisms included. The advantages of these indicators include better readability, reducing the incubation time at 24/48 hours and the possibility of carrying out incubation in the Central Sterilization

3rd Generation: This indicator detects the presence of an enzyme, a D-glucosidase associated with the spores, and provides a fluorescent readout which allows an assessment of the effectiveness of sterilization after 1hr (flash sterilization), 3 hours (sterilization steam) and 4 hours (ETO sterilization). Reading is performed in the incubator by fast red and green light (satisfactory sterilization) or (failure sterilization)

Basic method of using biological indicators

Place in the center of a package (surgical clothing) a biological indicator, by labeling its position, batch loading, date and number of autoclave, with full load in a normal cycle.

Then locate the package in the central part of the chamber and start the cycle.

Frequency of use can be daily, or weekly. After the cycle ends, it proceeds to bring it to 56 ° C incubator for the indicators used in autoclave (*G. stearothermophilus*). internal ampoule will break before placing in the incubator, so that the culture medium is in contact with the spores. At 48 hours, record the results:

Negative result: when the indicator does not change color according to the protocol, autoclave (violet) resulting in process proper or adequate sterilization.

Positive result: If the sterilization process was inadequate, the indicator changes color to yellow, which indicates that the bacilli are still alive and developed in the culture medium. In that case, inform, and immediately to track all packages in that batch sterilized for reprocessing.

"All sterilization processes should be monitored by physical monitors, chemical and biological indicators".

Conclusion

The CSSD, as a producer center of the hospital, is subject to different rules and laws that ensure patient safety and quality of health care. They must ensure the safety and effectiveness of the sterilization process, by controlling the quality of procedures and process validation. Wide is important to understand that the sterilization is achieved by various related practices that are essential for the continued use of the process for an extended period. Essential practical to maintain a validated state including calibration, physical measurements, physical integrators or indicators, continuous process control, change control,

preventive maintenance, periodic re-training. Therefore it is extremely important to understand the specific role played by each indicator and its proper use and correct interpretation.

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