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Complying with the Standards?

A closer look at the AS 5369:2023 Standards

4 very different control points – each representing different and important components of the process:

Equipment

Equipment monitoring is a way to find out whether or not your steriliser is doing its job properly. To monitor pre-vacuum steam sterilisers, you begin each day with a Bowie & Dick type test to detect air leaks, inadequate air removal, inadequate steam penetration and the presence of non-condensable gases, any of which can compromise sterility.

Load

Load monitoring is the specific proof that is provided to show that sterilisation conditions have achieved microbiological kill. This is accomplished by using either a BI or CI (performance equivalent to a BI) that may or may not be placed in a PCD.

Pack

Pack monitoring is defined as the use of chemical indicators for internal monitoring of packs, trays, containers and peel pouches. Internal pack monitoring verifies that the sterilant has penetrated to the point of placement of the chemical indicator in the pack and confirms that specific exposure conditions have been met. This is especially important for Operating Theatre Nursing Staff enabling them to comply with the Safe Surgical Checklist requirements for Sterility checking.

Exposure

Exposure monitoring products allow for steriliser operators to quickly determine if a pack has been exposed to a sterilisation process without the need to open the pack.

AS 5369:2023 Standards

This standard specifies the requirements and practices necessary for the effective and safe reprocessing of Reusable Medical Devices (RMD's). So, what does it say?

Assurance

2.4.3 (c):

Implement policies and procedures to ensure the safety and quality of reprocessed RMD's/other devices.

Policies

2.3.2:

Policies and procedures for reprocessing activities shall be documented and dated. At a minimum these shall include procedures for: (e) Routine monitoring and control of cleaning, disinfecting and sterilisation processes.

Demonstrate

8.1:

The process of routine monitoring and control is to demonstrate that the specified and validated cleaning, disinfection, packaging and sterilisation processes for an RMD/Other Device have been delivered to that Device.

Evidence

2.5.3.2 (b), (vi):

Sterilisation process records should include documented evidence of attainment of process parameters.

Risk Based Approach to Quality Systems

ACSQHC Standard 3 requires that reprocessing procedures align with applicable national and international standards. This includes adherence to AS 5369:2023, which provides guidelines for the reprocessing of reusable medical devices in both healthcare and non-healthcare settings. The standard mandates that facilities implement a Quality Management System (QMS) based on a risk-based approach. Appendix B of the standard offers an example of a risk management strategy. Facilities are expected to create their own systematic process for risk assessment.

The systematic approach includes seven steps which are outlined in the standard, including key elements of Risk:

- Risk Analysis – identifying hazards or threats in 4 categories (Physical, Chemical, Biological and Environmental). Hazards specifically listed as examples include Poor Steam Quality, Instrument set weight and wrapping of packs.
- Risk Evaluation – measuring impact of the threat or hazard.
- Risk Control – identifying control practices to implement addressing the threat or hazard.
- Risk Evaluation which discusses control measures implemented to control the threat or hazard, including importance of documentation and monitoring.

What is your evidence?

Implementing a quality system using a risk-based approach consistent with national and international best practice guidelines requires evidence; evidence that the parameters that are identified within the process are defined and have been met.

Fight SSI's from every angle

In Australia, SSI is the most common healthcare-associated infection occuring in approximately 3% of procedures.[1]

Sterilisation process monitoring devices include:

- **Physical monitors**
- **Chemical Indicators**
- **Biological Indicators**

Each of these devices plays a distinct and specific role in sterilisation process monitoring, and each is indispensable to sterility assurance [AAMI ST79].

How do you know the process always works?

- **Every Pack is different**
- **Every Load is different**
- **Every Cycle is different**

How do you know that an RMD has been exposed to the necessary conditions for steam sterilisation inside the pack?

1 Ref. Preventing Surgical Site Infections article June 2020 ICNISS

Document evidence of attainment of process parameters:

Control Point	Required Evidence	Example of Evidence	Documented Evidence within Facility to meet AS 5369:2023 available?
Equipment	Have you performed your daily check for adequate air removal?		Yes / No
Load	Have the load contents/orientation or weight affected steam penetration or air removal?		Yes / No
Pack	Have the contents inside the pack been exposed to the correct critical parameters?		Yes / No
Exposure	Is an external check available to verify the pack has been exposed to a process?		Yes / No

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