TECHNICAL TIP

2X PROCESSING FOR ETHYLENE OXIDE STERILIZATION

When validating an ethylene oxide process, it is advantageous for both the Customer and the sterilization facility to qualify a 2X process. A 2X process is the ability to subject the validated routine load configuration through two complete sterilization cycles.

Why would 2X processing be necessary?

The circumstances for 2X processing are rare, but nonetheless worthy of attention. Examples include but are not limited to: equipment malfunction, loss of power to the sterilization facility or positive microbiological results. If any of these situations occurred, it would be necessary to reprocess the load to achieve the required sterilization conditions.

What factors need to be considered?

While most medical devices can withstand a 2X process, it is important that all potential areas of negative impact are addressed:

- Functionality: does the device perform to the manufacturer's specifications after it has been exposed to a 2X process?
- Package Integrity: does the primary packaging maintain its integrity? Are there any seal breaches, pinholes or material degradation observed? This would also include secondary/tertiary packaging if present.
- Residues: are the ethylene oxide and ethylene chlorohydrin residues with the limits established in the ANSI/AAMI/ISO 10993-7 standard?

How is 2X processing established?

Establishing a successful 2X process can be performed during the initial sterilization validation. For those devices already validated with a 1X process, a separate study can be executed to evaluate the ability for 2X processing.

- During the validation: samples can be exposed to two full cycle processes and submitted for testing and evaluation
- Post-sterilization study: samples can be exposed to two full cycles OR they may be included on two routine sterilization cycles and submitted for testing and evaluation.
- While it is easier and more cost effective to qualify a 2X process during a validation study, the option to qualify the process at any time allows for flexibility with the manufacturer's schedule to execute it at their convenience.

What are the testing requirements?

There are various tests associated with a 2X processing qualification. Some may be the responsibility of the Customer while others are performed at a laboratory. Examples of tests are as follows:

- Functionality: performed by the Customer and/or manufacturer to verify that the device performs to specification.
- Package Integrity: performed by the laboratory to check the seal and package integrity of the primary, secondary and tertiary packaging (if present).
- Accelerated Aging: performed by the Customer or the laboratory to establish the expiration date of the device.
- EO/ECH Residue: performed by the laboratory to verify the levels of ethylene oxide and ethylene chlorohydrin remaining on the device after the 2X process.

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Conclusion

Validating an ethylene oxide process for 2X configuration helps a manufacturer avoid the need to discard expensive products and maintain the inventory supply chain in the event of an unforeseen event.

REFERENCES

1. ISO 11135:2014, Sterilization of health care products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices

2. ISO 10993-7:2008/(R) 2012, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

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