Steam Sterilization Monitoring and System Failures: Recalls

PIDAC Provincial Infectious Diseases Advisory Committee
Infection Prevention and Control

This checklist is an excerpt from Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices. It provides guidance related to situations that require recall of reprocessed medical equipment/devices and considerations to be included in recall procedures. For more information, please visit www.publichealthontario.ca or email ipac@oahpp.ca.

Inadequate reprocessing includes, but is not limited to, the following situations:

- ☐ The load contains a positive Biological Indicator (BI).[23]
- ☐ An incorrect reprocessing method was used on the equipment/device.
- ☐ Steam sterilizer indicates failure to reach correct cycle parameters (e.g., time temperature, pressure).
- ☐ Chemical Indicator (CI) or monitoring tape has not changed colour.
- ☐ There is doubt about the sterility of medical equipment/devices.[1,2]

A written procedure must be established for the recall and reprocessing of improperly reprocessed medical equipment/devices.[1,2] All equipment/devices in each processed load must be recorded to enable tracking in the event of a recall. Facilities should consider implementing commercial instrument tracking systems to facilitate identification of patients in the event of a recall.

The recall procedures should include[2]:

- ☐ Designation of department and staff responsible for executing the recall.[1]
- ☐ Identification of the medical equipment/devices to be recalled[1]; if recall is due to a failed BI, the recall shall include the medical devices in the failed load as well as all other devices processed in the sterilizer since the last successfully sterilized load.[1]
- ☐ Assessment of client/patient/resident risk.
- ☐ Procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies, if indicated.
- ☐ Surveillance of clients/patients/residents, if indicated.
- ☐ Quarantine of recalled items pending the results of investigation.
- ☐ Involvement of the facility's risk manager, if applicable.

Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.[14]

Reusable medical devices that have been recalled due to a reprocessing failure shall be reprocessed prior to use.

Recommendations

75. If a failed chemical indicator is found, the contents of the package shall be reprocessed before use. [CSA Z314.3]
76. A procedure shall be established for the recall of improperly reprocessed medical equipment/devices. [CSA Z314.0]
77. The recall procedure shall include assessment of client/patient/resident risk and a procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies if indicated. [CSA Z314.0]
78. Health care settings shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies. [CSA Z314.0]

References

The following references follow the order of original document. For full reference list please refer to Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices.

1. CSA Group. CAN/CSA-Z314.3-09: Effective sterilization in health care facilities by the steam process. Toronto, ON: CSA Group; 2009.
2. CSA Group. CAN/CSA-Z314.0-13: Medical device reprosessing - general requirements. Toronto, ON: CSA Group; 2013.

14. CSA Group. CAN/CSA Z314.8-08: Decontamination of reusable medical devices. Toronto, ON: CSA Group; 2008.

23. Health Canada. Infection control guidelines: hand washing, cleaning, disinfection and sterilization in health care [Internet]. Ottawa, ON: Health Canada; 1998 [cited 2017 Oct 23]. Available from: http://publications.gc.ca/collections/collection_2016/aspc-phac/HP3-1-24-S8-eng.pdf

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