Steam Sterilization Monitoring and System Failures: Recalls

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 include2:

☐ Designation of department and staff responsible for executing the recall.1

☐ Identification of the medical equipment/devices to be recalled1; 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.\textsuperscript{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.


