Place facility logo/header here

Procedure : Recall for Autoclave Failure (Steam Sterilization)

Date:

Revised Date:

Purpose: The sterilization process shall be tested, monitored with results recorded and audited. This procedure is for the recall of improperly reprocessed medical equipment/devices following a failure of biological indicators.

Procedure:

1. Include a BI in the sterilizer chamber once each day that the sterilizer is used to sterilize medical equipment and when changing load types.

2. Take the following steps after incubating and reading each BI that has been run through the sterilizer.

    a. If the BI indicates “no growth of organisms” (a negative BI), then document the finding in the sterilization log for that cycle.

    b. If the BI indicates “growth of organisms” (a positive BI), then proceed as follows:

        1. Notify the person in the office responsible for reprocessing of medical equipment that you have had a positive BI.

        2. Stop using the sterilizer until the reason for the positive BI is identified and the causes are resolved.

        3. Identify and quarantine all equipment and packages that were sterilized between the last successful cycle (which had a negative BI) and this failed cycle (with the positive BI).

        4. Check the sterilization log for the monitored sterilizer parameters during the failed cycle. Ideally, this will include the length of the cycle and the temperature and the pressure reached. Check, also, the status of chemical indicators on and, if visible, in packages from that cycle.

        5. Retest the sterilizer with a new BI and document the result.

            a) If the follow-up BI is negative (no growth of organisms), then the sterilizer is ready for use and any quarantined equipment in step 3 above can be returned for use if the relevant sterilization logs and chemical indicators otherwise indicate successful sterilization. (If the monitored sterilizer parameters and the chemical indicators did not suggest a problem with the sterilizer, then an assumption is made that a negative BI following a single positive BI indicates a false positive BI test and that no fault lies with the sterilizer.)

b) If the follow-up BI is positive, then a problem with the sterilizer is likely and it must be assumed that the sterilizer has failed. All equipment quarantined in step 3 above must be prepared for re-sterilization **but must not be sterilized in a sterilizer that failed a BI test until the sterilizer problem is resolved in accordance with this protocol.** That preparation must include re-cleaning, rinsing, drying and fresh wrapping or packaging (if the items are to be wrapped or packaged). The questionable sterilizer must not be used again until it has been serviced by a qualified technician and tested in accordance with section 6 below.

c) Notify the local Medical Officer of Health if medical equipment that was reprocessed in a failed cycle was used on a patient. The MOH, with help from experts in Infection Prevention and Control, will assist in determining the risk of disease transmission and the need for a look-back of potentially affected patients.

6. If the follow-up BI is positive, then the sterilizer must be serviced by a qualified technician and not returned to service until tested with three (3) successive challenges with fresh BIs in an empty sterilizer chamber. Any positive BIs from those challenges require further investigation by a qualified technician. Only three (3) consecutive negative BIs permits the return to service for the sterilizer. Re-sterilization of the quarantined packages which have been prepared in accordance with 5b above can now be performed with this sterilizer.

7. Document all service, testing, and other actions regarding the occurrence of a positive BI.

References:

1. Ontario Agency for Health Protection and Promotion (Public Health Ontario), Provincial Infectious Diseases Advisory Committee. Infection Prevention and Control for Clinical Office Practice. 1st Revision. Toronto, ON: Queen's Printer for Ontario; April 2015. https://www.publichealthontario.ca/en/eRepository/IPAC_Clinical_Office_Practice_2013.pdf

2. Ontario Agency for Health Protection and Promotion (Public Health Ontario). Provincial Infectious Diseases Advisory Committee. Best practices for cleaning, disinfection and sterilization of medical equipment/devices.3rded.Toronto,ON:Queen's Printer for Ontario; May 2013 https://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf

Place facility logo/header here

Algorithm for Autoclave Failure