

Positive (Failed) Biological Indicator Protocol for the Physician's Office

- I. For each new batch of biological indicators (BIs), determine that the BIs are viable by incubating one BI without running it through the sterilizer. The BI must indicate "growth of organisms" (a positive BI) or the batch must be returned as faulty.
- II. Include a BI in the sterilizer chamber at least once each day that the sterilizer is used to sterilize medical equipment.
- III. 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). This may involve notification of other offices or clinics if the sterilizer in question is used to reprocess equipment and packages for any outside facilities.
 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.
 - If the monitored sterilizer parameters were not as required by the manufacturer or the chemical indicators do not indicate a successful cycle, then investigate the cause of the cycle failure, fix any deficiencies and document the cause(s) and the remedies instituted. Recall all equipment that was processed during the failed and subsequent cycles and prepare them for re-sterilization. That preparation must include re-cleaning, rinsing, drying and fresh wrapping or packaging (if the items are to be wrapped or packaged). **Do not re-sterilize devices in a sterilizer that failed a BI test until the sterilizer problem is resolved in accordance with this protocol. Notify the local Medical Officer of Health if medical equipment that was reprocessed in a failed cycle has been 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. **Then proceed to step 5.**
 - If the monitored sterilizer parameters met the manufacturer's requirements and the chemical indicators indicate sufficient exposure to heat, **then proceed to 5.**

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

*The Public Health Act states:

26 A health practitioner, a teacher or a person in charge of an institution who knows of or has reason to suspect the existence of

- (a) a communicable disease in epidemic form,
- (b) another illness or health condition occurring at an unusually high rate,
or
- (c) a communicable disease or another illness or health condition that is caused by a nuisance or other threat to the public health shall immediately notify the medical officer of health of the regional health authority by the fastest means possible.

RSA 2000 cP-37 s26;2002 c32 s12;2007 c23 s4

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