

**BIOLOGICAL INDICATOR FAILURE INVESTIGATION CHECKLIST****Review Sterilization Cycle Parameters**

**Check the Sterilizer Display/Printout**  
*Confirm if there are any errors or alarms*

**Were critical parameters met for the intended cycle?**  
*Refer to your equipment operator manual to confirm critical parameters were met for the cycle ran, and are within acceptable range (i.e. time, temperature, pressure)*

**Review External Chemical Indicators, or Process Challenge Device (PCD) Indicators**

**Confirm the BI & CI Used are validated for the cycle**

**Confirm the PCD or BI is not expired**

**Did the CI Pass?**

*Yes:*

*No:*

**Review Storage of PCDs or BIs**  
*Stored outside allowed conditions?*

**Confirm the Expiration of the CI**

**Review Process for Handling and Placement of the PCD**

**If not using a pre-assembled PCD, was it correctly built?**  
*i.e. Correct pouch/material, BI ampule intact, and all procedures followed*

**Review Placement of PCD in the Chamber (How & Where)**  
*Ensure it was not on top of (or tucked under) a tray and placed in the proper location*  
*Typical VHP Placement: center, top shelf or near door*  
*Typical Steam Placement: bottom shelf, directly above the drain*

**Confirm Proper BI Activation & Incubation**  
*Was correct process followed, incubation temperature, and incubator used?*

**Investigate Potential Error in Preparation and Packing**

**Load configuration**  
*Overloading or improper organization of packs within sterilizer may can a BI failure*

**Load size and weight restrictions**  
*Ensure the load and devices were within size and weight restrictions of the sterilization cycle*

**Tray/Container configuration**  
*Over filling of containers or packages may cause a BI failure*

**Excess moisture, or improper drying of instruments**  
*Inspect for moisture on devices, and review that all drying procedures were followed*

**Proper Cleaning, Rinsing was completed**  
*If no errors have been found, the final step is to ensure that proper cleaning and rinsing procedures were followed*

**If the failure cannot be attributed to any cause listed –**  
*it's time to contact your facilities, biomedical, or service provider to determine if a repair is needed.*