Sterilization Failure Algorithm

| Air Detection Test Failure | Biological Indicator (BI) Failure | Chemical Indicator (CI) Failure | Physical Monitoring Failure |

Process box:
- ➤ Quarantine load, remove sterilizer from service
- ➤ Notify the Client Service Manager or designate in charge of CSR
- ➤ RE-Examine the failed indicator to ensure it was properly used, handled, and interpreted
- ➤ Examine other indicators and cycle parameters related to the affected load(s)

| Air Detection Test Failure | Biological Indicator (BI) Failure | Chemical Indicator (CI) Failure | Physical Monitoring Failure |

Air Detection Test Failure path:
- Retest the sterilizer with an Air Detection Test
- If the initial failure occurred in a BI monitored load: Re-wrap & Sterilize contents of that load.

Biological Indicator (BI) Failure path:
- Retest the sterilizer with a BI
- Decision: **Did test pass?**
  - YES → If the initial failure occurred in a BI monitored load: Re-wrap & Sterilize contents of that load.
  - NO → If failure (positive) BI, Send the BI to microbiology lab to confirm it is the test organism

- If the initial failure was an Air Detection Test Release loads if other monitors are normal.

Chemical Indicator (CI) Failure / Physical Monitoring Failure path:
- Decision: **Is cause of failure immediately identified and confined to one load or one package in a load?**
  - NO → Failure not immediately identified
  - YES → Correct the error and re-wrap and reprocess the item or load. If load has already been distributed, recall the load.

Recall all loads back to the last negative BI

Consult with ICP, Maintenance, and Sterilizer service representative to determine root cause of the failure. Operator error, procedural error, sterilizer malfunction, or utilities malfunctions or changes

- Sterilizer or Utilities malfunction is identified
- Cause of failure unknown
- Failure **CAN** be attributed to a cause other than sterilizer/utilities malfunction

- Service/repair sterilizer or utilities
- Correct error

- Run 3 consecutive Bix (all sterilizer types). Follow with 3 consecutive air detection test of dynamic air removal sterilizer
  - Test results fail → (back to Service/repair sterilizer or utilities)
  - Test result pass → Return sterilizer to service. Re-wrap and re-sterilize affected loads.