1. **Load Content and Configuration Assessment Checklist**

**Wet Pack Resolution Checklists**

In addition to completing the Wet Pack Log, the health care facility should answer the following questions and perform the recommended checks before the Local STERIS Service Technician arrives at the site.

**SPD Staff/Management**

**\* Customer Account Manager Observations (STERIS Clinical may assist)**

1. \* [ ]  Have you ever experienced moisture or water droplets on the interior or exterior of your packs?

If so, when did this occur (Month, year)?

1. \* [ ]  Do you have in place a wet pack tracking/log sheet and if so, what information do you capture?
2. \* [ ]  Do you check product manufacturer Indications for Use (IFUs) and keep on file for reference?
3. \* [ ]  Is staff training consistent as it relates to tray and load configuration practice?
4. \* [ ]  Do you make use of illustrations/photos indicating best practice and how is this communicated to the staff?
5. \* [ ]  Do you perform the recommended periodic testing of products and devices?
6. \* [ ]  Are you lining your shelves? Shelf lining may be compensating for poor steam quality.
7. \* [ ]  Are you draping (petticoating) your packages? Draping may be compensating for poor steam quality.
8. \* [ ]  Do you weigh your trays? Trays exceeding sterilizer manufacturer indications for use may retain excess moisture.
9. \* [ ]  Is the appropriate loading car being used with correct sized chamber?
10. [ ]  Check current packaging practice to include ALL accessories. Refer to standards such as AAMI ST79 for guidelines.
11. [ ]  Are rigid containers currently stacked on the loading car? Check manufacturer IFUs to verify if this is appropriate.
12. [ ]  How do you determine your spacing between packaging? Check that there is sufficient room for adequate steam circulation.

1. [ ]  Do you perform load segregation and if so, is this done manually or with an automated tracking system?
2. [ ]  Have you implemented quality systems to identify load weight?
3. [ ]  Is there a Quality Management System (QMS) program in place?
4. **Clinical Practices Assessment Checklist**

**SPD Staff/Management**

**\*Customer Account Manager Observations (STERIS Clinical may assist)**

1. \* [ ]  Do you have electronic access to your device manufacturer indications for use statements (IFUs)?
2. \* [ ]  If so, is it a home grown filing or a third party service?
3. \* [ ]  What is your schedule for updating OEM IFU information?
4. \* [ ]  Are your trays static or do they evolve based on events at the point of use (Customer adds/deletes instruments when without performing proper testing).
5. \* [ ]  Are the weights of your tray contents distributed evenly or do they slide when positioned on the sterilization carrier?

1. \* [ ]  What type of tray accessories are in use (silicone matting, holders, roll towels, peel pouches, etc)?
2. \* [ ]  Do you make use of wicking material and if so, have you performed and documented your product testing?
3. \* [ ]  Are there other uses for wicking material other than for under dense metal items and between trays layers?
4. \* [ ]  Are your instruments/devices properly dried prior to assembly?
5. \* [ ]  Do you perform the recommended product/device periodic testing?
6. [ ]  What is the percentage of inventory on hand of the following devices
	1. [ ]  Simple instrument trays (minor, major, ab hyst, etc)
	2. [ ]  Complex instrument trays (stereotactic, total joint trays, robotic)
	3. [ ]  Single tray configuration
	4. [ ]  Multi-tier tray configuration
	5. [ ]  Single packed instruments
	6. [ ]  Textile
	7. [ ]  Other (investigational devices IRB, pharmaceuticals, lab media/liquids)
7. [ ]  When was the last assessment performed on your washing/cleaning process? (automation vs. manual, automation in 444 (example) vs. cart washer?
8. [ ]  When changes are made in the washing/cleaning process is another assessment performed on your sterilization practice or is it assumed the change does not affect the current process?
9. [ ]  What is the training schedule of staff as it relates to clinical practices?
10. **Steam Sterilizer Performance Checklist**

**Facility and/or Biomedical Engineer (STERIS Service Technician may assist)**

1. [ ]  Check chamber strainers (steam inlet, water inlet, jacket and drain). These must be clean.
2. [ ]  Check incoming steam pressure –This must be between 50-80 psig dynamic.
3. [ ]  Check if water pressure is within specification 20-50 psig dynamic– this affects performance of the vacuum system.
4. [ ]  Verify the correct altitude setting (if applicable)
5. [ ]  Verify proper RTD placement.
	1. [ ]  Chamber/Recorder RTD set so the tip is positioned at the center of the chamber drain.
	2. [ ]  Jacket RTD set so that approximately 2 ½ in. is exposed past the end of the fitting.
6. [ ]  Run a vacuum leak test – A passing rate is less than 1.0 mmHg/min (Vac units only) – verifies that the piping is intact and there is no significant leakage
7. [ ]  Run a DART/Bowie-Dick Test - must pass
8. [ ]  Check the steam to chamber valve - a leaky valve will flow steam into the chamber during the dry phase and create wet loads, yet a DART or Bowie-Dick test will pass. A leak test should indicate a failure.
9. [ ]  What date was the last PM performed?
10. [ ]  Who performed the last PM?
11. [ ]  When was the sterilizer last calibrated?
12. [ ]  Who last calibrated the sterilizer?
13. [ ]  Has the calibration been verified since the wet packs first started appearing?
14. [ ]  Does the transfer carriage have drip rails installed?
15. [ ]  Are the drip rails functioning properly?
16. [ ]  Collect several good (dry load) and bad (wet load) cycle tapes for review by STERIS service.
17. [ ]  Are the instruments are coming out of the washer wet?
18. [ ]  Are the instruments being packed wet?
19. **Steam Sterilizer Performance Checklist (cont’d)**

**Facility and/or Biomedical Engineer (STERIS Service Technician may assist)**

1. [ ]  Has the sterilizer been properly leveled to ensure proper drainage? Even if the sterilizer has been installed for awhile it should be verified.
2. [ ]  Does the sterilizer show a wide water stain inside the chamber indicating excessive water pooling?
3. [ ]  Are chamber and jacket traps properly functioning? It is possible that function is fine with smaller loads, but not all loads.
4. [ ]  Check the sterilizer Pressure Regulating Valve (PRV) for excessive pressure fluctuations at the sterilizer.
5. [ ]  Is the PRV gap properly adjusted? Too small and superheat can occur; too large and the large amount of steam heats the load too fast and creates too much condensate.
6. [ ]  Check PRV function and Rebuild/Replace/Adjust PRV if needed.
7. [ ]  Check boiler capacity and steam line size. Use of a PRV can dampen fluctuations; adjust as necessary.
8. **Steam Supply Checklist**

The Facility’s engineering personnel should perform the following checks prior to the arrival of a STERIS service technician.

**Facility Engineer/Boiler Technician**

**HOUSE STEAM SUPPLY**

1. [ ]  Check the boiler water level control. High water level can cause carryover of liquid into the steam system. Check and correct for:
	1. [ ]  Faulty floats and dirty rods - Clean or replace floats and control rods
	2. [ ]  Boiler feed water valve malfunction – rebuild or replace boiler feed water supply valve if necessary.
2. [ ]  Inspect the sight glass. If the level is too high or too low there may be a malfunctioning control system or excessive demand. If the level fluctuates excessively or shows evidence of sediment/debris check and correct for:
	1. [ ]  Improper treatment of feed water
	2. [ ]  Insufficient blow down
	3. [ ]  Feed water supply valve defective– rebuild or replace boiler feed water supply valve if necessary.
	4. [ ]  Faulty floats and dirty rods - Clean or replace floats and control rods
3. [ ]  Test and monitor the boiler feed water and adjust the feed water treatment if necessary. Too little or excessive treatment may cause rust or foam in the distribution system resulting in trap failure or stained loads.
4. [ ]  Check internal/external boiler baffling. Inadequate baffling allows liquid to escape the boiler and enter the steam supply system. Install baffling properly.
5. [ ]  Check boiler pressure for insufficient or fluctuating steam pressure which will affect sterilizer operation and may cause carryover of boiler water into the steam system. Clean or replace faulty floats and dirty rods.

1. [ ]  Check boiler capacity. If there is inadequate boiler capacity the boiler size may need to be increased or sterilizer operation may need to be staggered.
2. [ ]  Check the boiler rotation schedule. Improper boiler shut down/start up sequence can introduce liquid into the steam delivery system because traps may lose prime. Follow the correct sequence of shut down/start up by bringing up the secondary boiler fully before shutting down the primary boiler.
3. [ ]  Check for changes in boiler loading due to seasonal changes. Seasonal variability can cause liquid to enter steam lines and traps exposed to excess condensate will lose prime and take excess time to recover. Physically verify trap operation after seasonal changes with boiler.
4. [ ]  Check for recent boiler maintenance and physically verify trap operation after major maintenance. Shutting down a boiler can cause excess condensate to accumulate in systems. Traps exposed to excess condensate will lose prime and will not function properly or take excess time to recover. Manual intervention is required to get components online.
5. **Steam Supply Checklist**

If an integral or stand-alone steam generator has been installed, the following checks should be performed by the STERIS Service Technician:

**STERIS Service Technician**

**INTEGRAL OR STAND-ALONE GENERATOR**

1. [ ]  Verify appropriate generator pressure set points.
2. [ ]  Verify that the blow down system is operating consistently. Insufficient blow down can cause debris or foam to be carried over into the steam system resulting in clogged traps or staining of sterilizer loads. Ensure that generator is blown down on a regular interval either automatically or manually.
3. [ ]  When was the last time a generator PM was done?
4. [ ]  When was the generator last descaled?
5. [ ]  Is the generator turning on/off about mid level in the site glass?
6. [ ]  Check for correct pressure on generator gauges.
7. [ ]  Have the probes and their associated wiring been checked to make sure they are controlling the water correctly?

1. [ ]  Intermittently high water level could cause water carryover into steam supply

**FULTON GENERATOR**

1. [ ]  Is the generator turning on/off about mid level in the site glass?
2. [ ]  Ensure ALL the water level and alarm probes are in the proper physical locations.
3. [ ]  Check the wiring against the schematic to ensure that it is routed properly. Do not assume connections are correct, as the schematic may have different wire numbers and colors, it is necessary to physically verify they are wired properly. An incorrectly wired ALWCO probe and PUMP ON probe can make water level control appear to be working, but the water levels may be too high and cause carryover.
4. **Piping Delivery System Checklist**

The Facility’s engineering personnel should perform the following checks prior to the arrival of a STERIS service technician.

**Facility Engineer**

1. [ ]  Inspect the steam supply back as far as allowable. Check trap location and size, and verify that traps are working. Failing or faulty traps can cause intermittent wet pack issues. A temperature check is not sufficient. If the traps are operating all the time, the trap is either malfunctioning and passing steam, or it is open because there is excessive water in the line and the trap is trying to remove it. If there is no action, the trap may be bad and backed up with water.
	1. [ ]  Facilities need to ensure they maintain traps and other components per manufacturers recommendations and keep a log of maintenance records
	2. [ ]  Spirax-Sarco or Armstrong are trap suppliers who can assist with trap evaluation, repairs and replacement.
2. [ ]  Ensure that the proper sized trap is located at end of facility steam supply line to sterilizers.
3. [ ]  Does the supply to the unit come off the top of the main steam line?
4. [ ]  Check the take off. Side or bottom piping take offs do not hinder condensate flow downstream: and condensate is carried into sterilizers. Reconfigure plumbing for top take off if necessary.
5. [ ]  Is there a dirt/drip leg located anywhere near connection to unit? It should be as long as the pipe diameter. Example - 6 inch supply line should have a drip/dirt leg 6 inches long
6. [ ]  If steam line ends at units is there a trap and a drip/dirt leg at the end of the line?
7. [ ]  Is there anything else connected to this system plumbing? Washers, Kitchen, Laundry that could be causing excess condensate or boiler carryover.
8. [ ]  What size steam header is feeding how many units?
9. [ ]  At what pressure is the steam in the steam header?
10. [ ]  Are there gauges on the incoming steam line? If not, install gauges.
11. [ ]  Has the accuracy of the gauges been verified by a calibrated device?
12. [ ]  What is the static steam pressure with no units in cycle but ready to run?
13. [ ]  What is the dynamic steam pressure with unit(s) in cycle? Check for reduced dynamic steam pressure during multiple unit operation.
14. **Piping Delivery System Checklist (cont’d)**

**Facility Engineer**

1. [ ]  Check the Pipe Slope. Pipes that are not sloped towards traps or dips/sags in piping between supports can cause excess condensate in steam lines that is not being removed by the traps: Re-slope and/or improve piping support if necessary.
2. [ ]  Check the pipe diameter. Insufficient pipe diameter increases steam velocity which reduces effectiveness of traps to consistently and effectively remove condensate from the steam lines. Use appropriately sized pipe (increase where necessary).
3. [ ]  Check the condensate return. The traps may not be able to remove condensate from steam lines because they are not designed for existing back pressure or excess back pressure on the condensate return system. Ensure proper trap design for system back pressure and ensure that back pressure does not exceed design limits.
4. [ ]  Check for proper functionality of the pump on condensate return systems with a condensate pump.
5. [ ]  Check filter. NOTE: A filter is designed to remove particulates in the steam but is not a remedy for bad upstream piping configuration and/or malfunctioning traps. Filters cannot completely remove large amounts of condensate.
6. [ ]  Check piping Insulation. Missing or damaged insulation can create additional condensate that my exceed designed trap capacity.

1. [ ]  Check if HVAC vents are blowing on piping. Adjust directional vents away from steam supply piping to prevent formation of excess condensate.
2. [ ]  Check environmental conditions for significant temperature differences in the work space.
	1. [ ]  Ensure that there is not significant temperature difference in work space by regulating heating and cooling system properly.
	2. [ ]  Ensure that there is air differential discrepancy between load/unload work spaces.
	3. [ ]  Adjust heating/cooling system seasonally to maintain proper temperature and humidity levels in prep/load/unload areas.
	4. [ ]  Verify proper amount of air exchanges per hour and negative air pressure between load/unload areas.