




PAI 010-01-030Y	<h1>PRE APPROVAL CHECKLIST</h1>	PAGE: 1 OF 6
	<h2>VALIDATION OF STEAM AUTOCLAVE OR DRY HEAT OVEN</h2>	


A U D I T	DATA Complete	COMMENTS If data is incomplete - state missing information
1. <u>Validation Protocol</u> Check that the Edition No. used is latest Edition. (Verify against list of Protocol Edition numbers and Effective Dates.)	YES <input type="checkbox"/> NO <input type="checkbox"/>	
2. <u>Overall Validation</u> Check that there are no absent pages and all pages are adequately filled in and properly signed. <input type="checkbox"/> Check that all signatures are present.	<input type="checkbox"/> <input type="checkbox"/>	
3. <u>Installation Qualification</u> Check that there are no absent pages <input type="checkbox"/> All pages are adequately filled in and properly signed.	<input type="checkbox"/> <input type="checkbox"/>	
List of change controls to equipment from last validation date up to present	<input type="checkbox"/> <input type="checkbox"/>	
List of instruments requiring calibration including ID Nos. category and whether calibrated or not.	<input type="checkbox"/> <input type="checkbox"/>	
	<input type="checkbox"/> <input type="checkbox"/>	

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	<h2>VALIDATION OF STEAM AUTOCLAVE OR DRY HEAT OVEN</h2>	


A U D I T	DATA Complete	COMMENTS If data is incomplete - state missing information
<u>System Drawings</u> Each drawing print has been verified as being correct and is suitably signed.	YES NO <input type="checkbox"/> <input type="checkbox"/>	
<u>Pressure Vessel Check (Autoclave Only)</u> Pressure vessel check sheets are adequately filled out and signed	<input type="checkbox"/> <input type="checkbox"/>	
4. <u>Operational Qualification</u> Check that no pages are missing <input type="checkbox"/> All pages are adequately filled out and signed.	<input type="checkbox"/> <input type="checkbox"/>	
<u>Chamber Leak Rate Test (Autoclave Only)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled. <input type="checkbox"/> Check that all attachments are in place	<input type="checkbox"/> <input type="checkbox"/>	
<u>Quality of Steam (Autoclave Only)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled. <input type="checkbox"/> Check that all attachments are in place	<input type="checkbox"/> <input type="checkbox"/>	
<u>Interlock Check</u> Check that all acceptance criteria as stated in the protocol are fulfilled.	<input type="checkbox"/> <input type="checkbox"/>	

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A U D I T	DATA Complete	COMMENTS <small>If data is incomplete - state missing information</small>
<u>Safety Features Tests (Alarms Tests)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled.	YES NO <input type="checkbox"/> <input type="checkbox"/>	
<u>Fan Operation (Oven Only)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled.	<input type="checkbox"/> <input type="checkbox"/>	
<u>Fans Operation Test (Oven Only)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled.	<input type="checkbox"/> <input type="checkbox"/>	
<u>Excess Temperature Cut-Off Test (Oven Only)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled.	<input type="checkbox"/> <input type="checkbox"/>	
<u>Inlet, Re-circulation and Exhaust Filters Test (Oven Only)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled. <input type="checkbox"/> Check that all attachments are in place.	<input type="checkbox"/> <input type="checkbox"/>	
<u>Particulate Matter Tests (Oven Only)</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled. <input type="checkbox"/> Check that all attachments are in place.	<input type="checkbox"/> <input type="checkbox"/>	

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A U D I T	DATA Complete	COMMENTS <small>If data is incomplete - state missing information</small>
<p>Chamber Pressure Test (Oven Only) Check that all acceptance criteria as stated in the protocol are fulfilled. Check that all attachments are in place.</p>	<p>YES NO</p> <input type="checkbox"/> <input type="checkbox"/>	
<p><u>Empty Chamber Heat Distribution Test</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled. <input type="checkbox"/> Check that all attachments are in place.</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p>Check that number of tests as required by the protocol are performed and are within limits.</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p><u>Paper Feed Rate Test</u> <input type="checkbox"/> Check that all acceptance criteria as stated in the protocol are fulfilled. <input type="checkbox"/> Check that all attachments are in place.</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p><u>Software Program Test (Cycle Test)</u> Check that all acceptance criteria as stated in the protocol are fulfilled.</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p>Check that all attachments are in place.</p>	<input type="checkbox"/> <input type="checkbox"/>	
<p>Check that all cycles used in the equipment are checked</p>	<input type="checkbox"/> <input type="checkbox"/>	

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A U D I T	DATA Complete	COMMENTS <small>If data is incomplete - state missing information</small>
<u>SOP Verifications</u> Check that the SOPs exist and are verified.	YES NO <input type="checkbox"/> <input type="checkbox"/>	
SOP - Operation of Equipment	<input type="checkbox"/> <input type="checkbox"/>	
SOP - Cleaning and Sanitation of Equipment	<input type="checkbox"/> <input type="checkbox"/>	
SOP - Preventative Maintenance Program	<input type="checkbox"/> <input type="checkbox"/>	
SOP - Filters Handling Program	<input type="checkbox"/> <input type="checkbox"/>	
<u>Performance Qualification</u> <input type="checkbox"/> Number of loading patterns validated: _____ <input type="checkbox"/> Presence of calibration of thermocouples according to relevant SOP (edition effective on date of validation). <input type="checkbox"/> Check that each of the loading patterns were validated according to the protocol, i.e.: <input type="checkbox"/> Number of runs as stated in the protocol. <input type="checkbox"/> All acceptance criteria fulfilled.	<input type="checkbox"/> <input type="checkbox"/>	

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A U D I T	DATA Complete	COMMENTS If data is incomplete - state missing information
<u>Final Report</u>	YES NO	
Check that all discrepancies are clarified in the Final Report.	<input type="checkbox"/> <input type="checkbox"/>	
Final Report is signed-off and the signature is dated	<input type="checkbox"/> <input type="checkbox"/>	
Have all discrepancies been followed up and signed-off and closed by the QA	<input type="checkbox"/> <input type="checkbox"/>	
All report pages are numbered and contain no "white-out or overwriting"?	<input type="checkbox"/> <input type="checkbox"/>	
The Final Report is signed-off by QA and signed as "complete and closed"	<input type="checkbox"/> <input type="checkbox"/>	