

Example of an OQ protocol for an autoclave:

AUTOCLAVE OQ
<p>Objective</p> <p>To determine that the autoclave model # _____, installed in building ____, room ____ operates according to specifications, to determine the heat /steam distribution in the jacket and empty chamber and to record all relevant information and data to demonstrate it functions as expected.</p>
<p>Scope</p> <p>a) For new installation, modification, replacement, or relocation of any critical component of the autoclave.</p> <p>b) If there is a contamination problem.</p> <p>To be performed after the IQ has been completed and approved.</p>
<p>Responsibility</p> <p>Supervisor of the Department where the autoclave is located is responsible for writing the protocol, supervising the performance of the OQ, verifying the data and writing the OQ report.</p> <p>QA is responsible for approving the protocol and reviewing and approving the data and conclusions.</p>
<p>Equipment and Documents</p> <p>Example of calibration instruments required are:</p> <p>thermocouples, pressure calibrator, vacuum calibrator, temperature detectors and probes, timers, temperature bath, flow meters. (Certification methods should be referenced)</p> <p>SOP# ____: Operation, Maintenance, and Calibration of the Autoclave</p> <p>Training records for personnel operating and maintaining the autoclave.</p> <p>The calibrating instruments must be certified before being used for calibrating the autoclave.</p>
<p>Procedure:</p> <p>Typical critical parts of the autoclave to be calibrated are:</p> <p>temperature sensors, pressure sensors, pressure gauges, pressure switches, pressure transmitters and input/output transmitter.</p> <p>Typical alarm points to be checked on the autoclave are:</p> <p>under or over temperature, evacuation too long, sterilization too long, vacuum system failure, door open, failure reading temperature or pressure or both, failure reading load, pressure in chamber with door unsealed, chamber flooded, insufficient vacuum level to perform leak test, low battery,</p> <p>Proceed with the testing of the functions of the autoclave.</p>