

Example of an Autoclave IQ protocol:

AUTOCLAVE IQ

Objective

To demonstrate that the Autoclave manufactured by _____, model # _____ and accessories installed in building _____, room _____ conforms to the purchase specifications and the manufacturers literature, and to document the information that the equipment meets specifications.

Scope

For new installation, modification, replacement, or relocation of any critical component of the autoclave.

Responsibility

Supervisor of the Department where the autoclave is located is responsible for writing the protocol, supervising the performance of the IQ, verifying the data and writing the IQ report.

QA is responsible for approving the protocol and reviewing and approving the data and conclusions.

Systems/Equipment

Give a brief description of the autoclave indicating the manufacturer and model name/number, where it is located, what materials it will be sterilizing, any accessories that accompany it (e.g. carts) and provide a short description of how the autoclave functions.

Component List

Typical major components associated with autoclaves are:

autoclave chamber, baffles, shell insulation, frame, doors, door seals, temperature detectors and probes (RTDs), temperature recording chart, safety valves, vacuum pump, side door motor, sterilization cart, pressure transmitters and gauges, microcomputer control, chamber high water sensor .

Procedure

Fill in the prepared checklists with the detailed mechanical and electrical specifications, drawings, etc. (as itemized in the IQ format) for each component as listed in the IQ format.

The individual component checklist includes a space to record the information plus any deviations found during the installation check.

Reporting

Responsible person verifies that the information is complete, prepares the Deviation Report and the Installation Qualification Report and, submits to QA for review and approval.