Steril-Q™ Validation and Documentation Services

Steril-Q™ includes an array of documentation, tools and expertise required to successfully qualify and validate a new or existing autoclave within accepted IQ/OQ/PQ protocols.

Steril-Q™ program components include installation, operation, and performance qualification to help you comply with the current USA and International Standard for steam sterilization as set forth in ISO 17665.

Consolidated offers the following component programs individually or as a complete suite of professional services.

IQ Installation Qualification

Installation Qualification (IQ) provides documentary evidence that the equipment has been built and installed to specification, and that all supporting services (i.e., utilities such as electricity, water, and steam) are available and connected properly. The IQ process methodically documents all aspects of the installation, the machine components, and any testing equipment used to provide a complete, closed-loop assessment. In addition, IQ includes NIST traceable calibration verification of the unit's critical components.

- IQ is typically carried out concurrently with or after the equipment installation at the user's facility. The IQ is performed by following a specific IQ protocol tailored for each piece of equipment.
- IQ can be performed by a third party using the Consolidated IQ Template, or by an authorized Consolidated Steril-Q™ representative following the IQ Template.

OQ Operation Qualification

Operational Qualification (OQ) provides documented evidence that the sterilizer operates in accordance with design specifications. The OQ validation examines the autoclave's ability to run the sterilization process correctly and to respond appropriately to error conditions, assuring that the sterilizer performs as intended.

- Alarm conditions and expected results, as well as vacuum leak test performance (if applicable) are verified.
- Empty chamber temperature mapping is performed to verify and document that the temperature range delivered throughout the empty autoclave is within required specifications.
- If required, verification of sterilization efficacy using biological indicators (BI) may be carried out to meet a strict interpretation of the standard. (BI testing with a full load is performed in the Performance Qualification phase.)
- OQ can be performed by a third party using the Consolidated OQ Template, or by an authorized Consolidated Steril-Q™ representative following the OQ Template.

PQ Performance Qualification

Performance Qualification (PQ) documents the sterilizer's ability to achieve the desired outcome (i.e. sterilization of specific loads when operated in accordance with predefined operating procedures).

- The sterilizer is tested with actual production loads.
- Thermocouples are placed within the load items at positions presenting process challenge locations.
- In addition to temperature mapping, biological indicators (BI's) may be used to demonstrate compliance with all user requirements.
- Prior to PQ all required methods and Standard Operating Procedures must be finalized and operator training completed.

SQ Steam Quality Testing

Steam Qualification (SQ) is essential to the proper operation of the steam sterilizer. Consolidated steam quality testing is available to document the suitability of the steam delivered to the chamber, and to ensure compliance with the requirements of ISO 17665. A successful test result ensures a predictable level of process lethality.

FAT Factory Acceptance Test

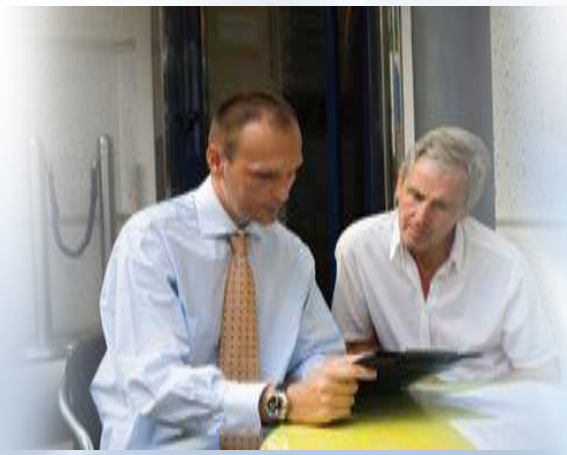
Factory Acceptance Testing (FAT) is a process used to evaluate the sterilizer after assembly and to verify that its operation complies with design specifications prior to shipment. Through this process all sterilizer components and controls are confirmed. Sterilizer functionality is qualified, verified and documented. Any deviation or abnormalities observed during testing are documented in an exception report and remediated prior to shipment.

- The FAT is performed at Consolidated's corporate headquarters before the unit is shipped.

Consultative Services and Program Pricing

For more information about Consolidated IQ/OQ/PQ and SQ testing services or other specialized testing required to meet internal or third-party criteria, contact Consolidated or your authorized Consolidated sales or technical service representative.

Service	Description	Order Number
IQ Template Only	The customer provides site utilities and all labor. Consolidated provides the IQ Template only.	IQT
IQ Template, Execution and Final Printed Report	The customer provides site utilities. Consolidated supplies labor, implementation/execution, IQ Template, test equipment, and calibration standards. Consolidated will deliver a completed IQ Template.	IQF
OQ Template Only	The customer provides cycle parameters with assistance from Consolidated, plus all utilities, technical support, and labor. Consolidated provides the OQ Template only.	OQT
OQ Template, Execution and Final Printed Report	The customer provides site utilities. Consolidated supplies labor, implementation/execution, OQ Template, biological indicators, and all other necessary software, hardware, and standards. Consolidated will deliver a completed OQ Template.	OQF
PQ Template Only	The customer provides actual products to be sterilized or a representative sample, plus all utilities, technical support, and labor. Consolidated provides the PQ Template only.	PQT
PQ Template, Execution and Final Printed Report	The customer provides site utilities and actual products to be sterilized (or a representative sample). Consolidated supplies labor, implementation/execution, PQ Template, biological indicators, and all other necessary hardware and software. Consolidated will deliver a completed PQ Template.	PQF
SQ Template Only	The customer provides sterilizer, steam source, all utilities, test equipment and labor. Consolidated provides the SQ Template only.	SQT
SQ Template, Execution and Final Printed Report	The customer provides sterilizer, steam source, and site utilities. Consolidated supplies labor, implementation/execution, SQ Template, test equipment, standards, and technical support. Consolidated will deliver a completed SQ Template.	SQF
FAT	Consolidated will deliver a completed Factory Acceptance Test form.	FAT



CONSOLIDATED STERILIZER SYSTEMS

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