



Equipment Qualification Process

Definitions:

- Installation Qualification (IQ): Establishes the instrumentation was received as specified and documents the proper installation and operability according to manufacturer standards.
- Operational Qualification (OQ): The process of demonstrating that an instrument will function according to the manufacturer's operational specifications under normal laboratory conditions.
- Performance Verification (PV): A testing procedure designed to test the analytical instrument's functional performance to factory published specifications.

Service Benefits:

- Provide the evidence needed to satisfy the requirements of international regulatory and quality agencies.
- Eliminate the need for laboratory validation specialists and quality assurance/quality protocols for the tested instruments.
- Ensure that the instrument is performing according to the manufacturers specification.
- Follow the same procedures and provide uniform documentation from laboratory to laboratory, worldwide.
- Decrease the risk of financial loss caused by noncompliance.
- Ensure confidence in the integrity of their measurements, with traceable documentation that give them, their customers, and regulatory agencies a complete record.
- Trained and certified service engineers perform the procedures.
- SCC provides calibrated and traceable tools, testing equipment and standards needed to qualify the instrument.
- SCC is factory trained in the operation of the instrument.

Included in the service:

All documentation and reports used to determine instrument performance and certifications for the test equipment used.

Calibrated and certified test equipment such as flow meters and digital thermometers.

Parts necessary to run the tests including columns, fittings, and standards.

Labor hours to run the test procedures.

Final report and validation sticker.

Test Procedures:

System maintenance:	This must be performed prior to the Operational Qualification to ensure proper performance. By performing the proper maintenance, one identifies the tested equipment and evaluates the general fitness of the system. The maintenance procedure includes a check of the system's basic electronic functionality and safety features.
System preparation:	Installation of checkout column System conditioning
Inlet leak/pressure tests:	These tests include the evaluation of each inlet for leaks with a timed pressure test and verification of pressure accuracy using a calibrated manometer.
Oven temperature tests:	This test compares the instruments oven temperature against a calibrated temperature probe.
Detector noise test:	This test evaluates each detector for ASTM noise; wander and drift using the Chemstation's "Performance and Noise" report functions.
Chemical performance tests:	Evaluates the performance of an "analytical channel" (inlet and detector combination) by one manual injection of a test sample. The manual injection results are evaluated for absolute detector response. Systems with an autosampler are evaluated by injecting a series of five test samples. The results are evaluated for absolute detector response, reproducibility of detector response, and retention time reproducibility.

Caution: The Qualification Process is sold as a per incident OQ/PV (pass or fail). SCC does not guarantee a positive outcome of the procedure. You have the option (in case the instrument does not pass the tests) to schedule a repair with the engineer and retest the product (after the repair is completed) for an additional charge.