



VALIDATIONS

The purpose of this page is to explain and identify our theory of chamber qualification.

For purposes of clarity, *validations* are referred to throughout the corresponding literature and relevant documentation as *qualifications*, due to the fact that we are specifically engaged in assisting our clients with their Validation Process.

In order to provide a trouble-free qualification, we recommend that a start-up commissioning checklist be performed prior to the execution of the protocol. This will ensure that your equipment is performing in accordance with the manufacturer's specifications, and that all necessary documentation is in place.

A qualification package should consist of calibration records of all instrumentation used during the qualification and also provide documented evidence that the chamber's instruments are in a current calibrated state.

The Installation Qualification (IQ) is utilized for providing documented verification that all key aspects of the design, procurement, and installation adhere to the design intention. One example of IQ-related services is the documentation and verification of serial/model numbers against those provided in corresponding submittals or quotations.

The Operational Qualification (OQ) is utilized for providing documented verification that the systems and sub-systems perform as intended at all anticipated operating ranges (normally performed with an unloaded chamber).

The Performance Qualification (PQ) is utilized for providing documented verification that the process does what it purports to do (normally performed with either a simulated or actual product load in the chamber).



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A Kaye Validator 2000 is used exclusively for the execution of our qualification testing. Prior to the execution, all thermocouples and Relative Humidity (RH) sensors used for data collection will receive an onsite two-point calibration and a mid-point verification. The OQ is then tested for the duration specified.

The PQ is subsequently tested for the duration specified. After the PQ test is complete, the thermocouples and RH sensors receive three-point calibration verifications. The data (maximum and minimum data) will be collected and presented using the Kaye Qualification Report and Qualification Summary Report. Any deviations encountered during testing are documented in the protocol with an approved deviation report and mentioned again in an executor's summary report.

The executor's summary report will be provided after the testing is complete. Qualification data is reported in both table and graphical form in the executor's summary report, in order to visually display the results.

A tailored protocol can be provided and include any or all of the following; IQ/OQ/PQ. Qualification protocols are submitted for your review (with approved purchase order) and approval prior to the execution of the protocol.

A start-up commissioning checklist and calibration services are also available by Darwin Chambers. Please see our preventive maintenance and calibration page for more information.