

Guidance 032 Laboratory Equipment Qualification

For simple and moderate equipment the OQ requirements may be replaced and supported by the initial calibration.

For complex systems, OQ should include critical instrument test parameters defined for the intended use and purpose of the instrument. Calibration data may be used to support OQ of complex instruments, but cannot replace OQ.

OQ should focus on the operation of each component. The OQ may be conducted according to the manufacturer's instructions or recommendations (if available), focusing on each components operation. Alternatively, tests that involve the entire system may be substituted for component testing.

10. For Moderate and Complex Equipment that Stores Data Electronically, procedures and processes should be in place to ensure data integrity and security.

For complex equipment, aspects of system security, configuration, and electronic data and electronic signatures should be addressed in a local Site procedure or equipment specific protocol or plan.

Supplemental qualification tests should be performed for complex equipment with personal computers (PC) connected to the server to verify proper configuration of the system and to verify establishment of the proper user permissions.

11. Performance Qualification (PQ) should ensure that the instrument is performing as specified, and configured in accordance with the intended use in the laboratory.

The PQ instructions or protocol for an off-the-shelf piece of equipment, including vendor provided documentation, should be approved by the Quality Authority prior to execution.

For moderate equipment, the PQ requirements may be met through the initial calibration provided that the calibration includes the range of intended use at the Site, which is conducted as part of the qualification exercise.

For complex equipment, PQ should include testing using all modules of the equipment and should be reflective of the intended end-use.

PQ may be achieved through method transfer or method validation if the intended end use of the equipment is addressed.

Moderate equipment routine use of system suitability and/or control samples may satisfy PQ requirements.

12. Periodic Reviews should be performed to determine the current status of the equipment and the need for re-qualification, and shall include at a minimum, the review of: