5.2.3.2 A risk assessment is performed to ensure that the instrument is safe to be used
5.2.3.3 Training has been performed and documented

5.3 Operational Qualification (OQ)

5.3.1 OQ documents that the instrument operates in accordance with site requirements, specifications and manufacturer's recommendations.
5.3.2 The OQ documentation must include:
5.3.2.1 A unique instrument number
5.3.2.2 Instrument description
5.3.2.3 Instrument location
5.3.2.4 The qualification procedure
5.3.2.5 Qualification data
5.3.2.6 Signature and date of colleague and/or vendor executing the OQ

5.4 Performance Qualification (PQ)

5.4.1 PQ documents that an instrument can accurately quantify specified results using a specific quantitative analytical method on a consistent basis. Equipment performance qualification activities cannot begin until the IQ and OQ have been satisfactorily completed.

5.4.2 PQ documentation must include:
5.4.2.1 A unique instrument number
5.4.2.2 Instrument description
5.4.2.3 Signature and date of colleague executing PQ
5.4.2.4 Procedures to ensure and verify that the entire system is performing satisfactorily.

5.5 Qualification of Existing Equipment

5.5.1 Retrospective qualification can be performed on established equipment. It does not require as detailed IQ, OQ or PQ as new equipment. Routine calibration data can be used to support and verify the performance of equipment.

5.5.2 For existing HPLC systems, firmware update for any module should have a Site Change Control raised for the instrument to be qualified as per SOP *QMS 125 Change Management System,* and a qualification protocol (qualification protocol number obtained from the logbook) written detailing the IQ/OQ/PQ procedure to be performed.

5.6 Post Service Qualification for Instrumentation

5.6.1 **HPLC Systems**

5.6.1.1 When HPLC systems are repaired / serviced, it must be assessed as to whether the repair is considered major or minor (refer to **Table 1**).

5.6.1.2 When a major repair / service / replacement takes place, PQ on the entire system needs to be carried out according to the procedures detailed in SOP *LAB-090 HPLC Reproducibility, Column Performance and Testing Guidelines.*

5.6.1.3 When a minor repair takes place, calibration of the module / component that was repaired or replaced will be assessed and performed accordingly.
Note: Cleaning or replacement of check valves is not considered to be either a major or minor repair and no qualification of the instrument is required.

