

Operational and performance qualification in detail.

A: Operational Qualification (OQ):

It is the process of testing to ensure that the individual and combined systems function to meet agreed performance criteria and to check how the result of testing is recorded. The purpose is to ensure that all the dynamic attributes comply with the original design. Each of the instrument's function are checked to ensure that they conform to the manufacturer's Specifications.

This includes the use of certified, traceable electrical stimulators and standard to verify that the equipment is processing input signals correctly.

Performance qualification:

→ It is also called process qualification. is the process of testing to ensure that the individual and combined systems function to meet agreed performance criteria on a consistent basis and to check how the result of testing is recorded.

→ The purpose is to ensure that the criteria specified can be achieved on a reliable basis over a period of time.

→ It is for its routine analytical use is checked to ensure that this complies with its specification.

→ control standards of similar values to the intended test samples must be used for PQ.

→ It is the process of demonstrating that an instrument consistently performs according to a specification appropriate to its routine use.

→ It should be performed on a daily basis & whenever the instrument is used. The test frequency depends not only on the stability of equipment but also on everything in the system that may contribute to the analysis results.