

Can I use the HSQ Kit for Installation Operational or Performance Qualification - FAQ

The HSQ™ Kit is designed for Performance Qualification.

Procedures pertaining to IQ will typically not require any kit such as this. IQ will entail a description of the instrument (e.g. make, model, serial number, software version, location), verification that the instrument has been delivered undamaged, performance of any preliminary instrument diagnostics, and connection to a network or data storage system. For OQ, the HSQTM solutions can be used where applicable. As in IQ, some of these qualifications will not require a kit such as *fixed parameters*. These parameters are determined once and do not need to be measured again (e.g. the instrument's physical dimensions, weight, voltage inputs, etc.). In the case of parameters like *instrument function tests*, the HSQ solutions may be appropriate but the user will have to define their own SOPs.

From USP <1058>:

Installation Qualification (IQ) - The documented collection of activities necessary to establish that an instrument is delivered and designed as specified, and is properly installed in the selected environment, and that this environment is suitable for the instrument.

Operational Qualification (OQ): The documented collection of activities necessary to demonstrate that an instrument will function according to its operational specification in the selected environment.

Performance Qualification (PQ): The documented collection of activities necessary to demonstrate that an instrument consistently performs according to the specifications defined by the user, and is appropriate for the intended use.

Click <u>HERE</u> for PQ & HSQ Kits ordering information and pictures.

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