INSTRUMENT QUALIFICATION

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WHAT IS THE GOAL OF INSTRUMENT QUALIFICATION

- Instrument qualification is “a series of processes which establishes documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specification and quality attributes.

TYPES OF QUALIFICATION

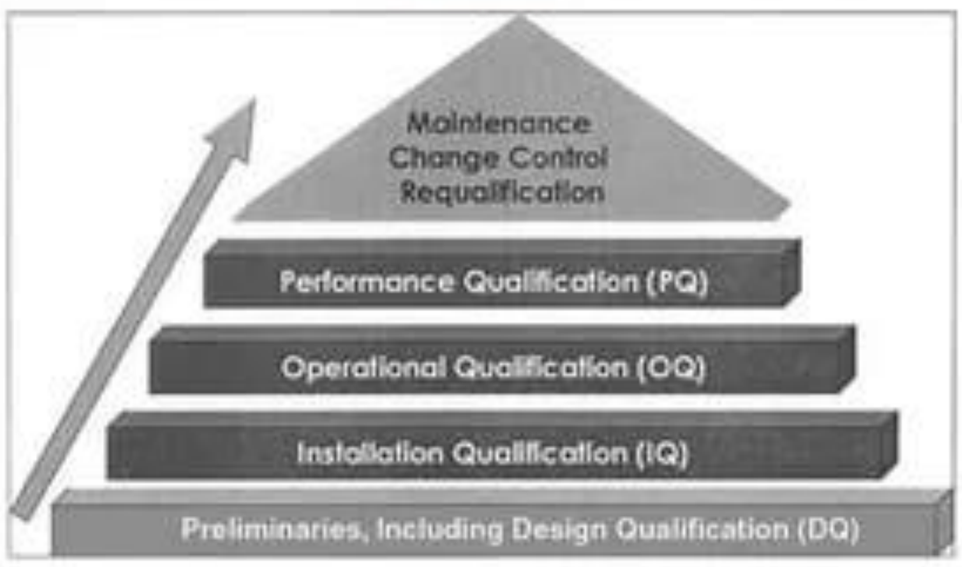

Figure 1 *Steps of qualification.*

Photo shows steps of Instrument Qualifications steps.

1. DESIGN QUALIFICATION [DQ].

- includes activities that define the design elements of the instruments such as functional and operational specifications as well as vendor selection criteria. DQ can be performed by the manufacturers, developers

2. INSTALLATION QUALIFICATIONS (IQ)

- ESTABLISHES THAT THE INSTRUMENT IS RECEIEVED AS DESIGNED AND SPECIFIED THAT IT IS PROPERLY INSTALLED IN THE SELECTED ENVIRONMENT AND THAT THIS ENVIRONMENT IS SUITABLE FOR THE OPERATION OF THE INSTRUMENT

3. OPERATIONAL QUALIFICATION (OQ)

- at owner’s site after installation
- The process of demonstrating that an instrument will function according to the operational specification in the selected environment

4. PERFORMANCE QUALIFICATION (PQ)

- he 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. It requires performance checks to be made through a series of tests

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