

POLARIMETER QUALIFICATION

In today's regulatory environment qualification of equipment is required before reported any readings. This insures correct installation, expected operation, and performance to specification in the users' laboratory.

THE QUALIFICATION PROCEDURE USUALLY CONSISTS OF FOUR PARTS

PRE QUALIFICATION CHECK this procedure checks whether the equipment, needed accessories, spares and calibration materials are received and whether they are as per the purchase order or not.

INSTALLATION QUALIFICATION (IQ) qualifies that the equipment is installed in a suitable location, and whether the needed inputs and outputs like water, power, air, exhaust etc. are properly connected as per manufacturers' recommendation.

This is a relatively straight forward procedure for a well packaged equipment like the DigiPol, since all the needed facilities like printer, PC hook up, coolant plumbing etc. are built in. It is only necessary to check for a stable operating table, nearby power outlet, and adequate space behind it for ventilation.

OPERATIONAL QUALIFICATION (OQ) qualifies that the equipment as installed is operating as expected. It is necessary to cycle the equipment through all of its operational capabilities to check proper operation. The OQ procedure written by Rudolph Instruments for the DigiPol checks the operation of every single key stroke combination to essentially test every line of software inside, to ensure its proper operation.

PERFORMANCE QUALIFICATION (PQ) checks whether the equipment is merely operating as intended. PQ on the other hand, goes one step beyond that, and checks whether the equipment is performing to the published spec. Performance check for a Polarimeter consists of checking its calibration and linearity. The PQ suggested by Rudolph Instruments checks the basic calibration of the equipment with stable NIST traceable Quartz Rotation Standards as they alone have the requisite accuracy to test DigiPol with its $\pm 0.05\%$ accuracy. A further series of measurements with a solution of NIST certified Sucrose or Dextrose checks the linearity of the equipment over a wide range of angles.

The comprehensive Qualification procedure that is available for DigiPol, complies with cGLP/ GMP requirements is highly valued ranked by the customer users as one of the most comprehensive and extensive procedure available for any Polarimeter system.