

# Prep to Process Instrumentation & Qualification Services: Terminology



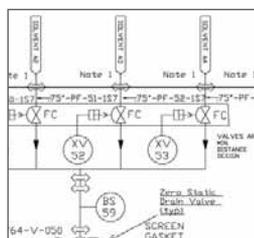
The Varian P2P group can meet our customers' design, installation, qualification, and service needs. Our comprehensive range of support services includes:

- ▶ Site preparation guidance, complete installation, and on-site instrument and software training
- ▶ Tools built-in to the LC ReSponder™ Control Software to assist the customer in meeting all 21 CFR Part 11 compliance requirements.
- ▶ Optional qualification support for software and system DQ/IQ/OQ/PQ

Varian's reliable preparative instruments and superior support enhance productivity, minimize downtime, and maximize our customers' return on their investment. Please also refer to the Varian Global Care Program qualification services and the Analytical Instrument Qualification (AIQ) documents for Varian non-Prep to Process products.

## Instrumentation Terminology

The *Process & Instrumentation Diagram (P & ID)* has a very important place in the documentation. In the simplest possible way, this drawing documents the complete fluid stream process, the plumbing requirements, and the various instrumentation components (pumps, detectors, valves, etc.) to be incorporated into the customized skid system. These drawings provide the basic details on all instrumentation engineering. They are prepared with easily recognizable instrumentation symbols, and the diagram is a "simplified" version of the full system, usually on one page. The P & ID is supplied, along with the quotation for the skid system/column.



*Explosion Proofing (XP/ATEX)* involves adding various safety mechanisms to the skid instrument design to permit the isolation of electronic components that could be exposed to the vapor or liquid used in the separation process. Explosion proofing (XP in the US and ATEX in the EU) is a fire hazard safety mechanism. Basically, this involves isolation of the electronics in a pressurized cabinet that is flushed with an external source of air or nitrogen, which leaks slowly out of the cabinet, into the work area atmosphere, at a fixed rate. Vapor sensors that can shut the system down electrically can also be added to monitor the atmospheric vapors in the work area for added safety. Explosion proofing can be quoted as an integral part of a system, or it can be an option to the basic skid system.

*CE Certification* is provided for systems and Load & Lock columns to meet all the European required pressure and electrical standards.

NOTICE: This document contains references to Varian. Please note that Varian, Inc. is now part of Agilent Technologies. For more information, go to [www.agilent.com/chem](http://www.agilent.com/chem).

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The *Factory Acceptance Test (FAT)* is the process of demonstrating to the customer the functionality of a customized skid product within a Varian factory or assembly site, prior to shipping the system/column to the customer's site. These testing procedures are primarily associated with customized Skid systems/columns. This test is done before the final installation at the customer's site. The FAT is used to verify that the product meets the purchased specifications so that the customer can approve shipping of the unit, and Varian is guaranteed that the customer will accept the shipment. The FAT is not a requirement, but is highly recommended, especially for customized skid systems. It is included in the standard system price. If a FAT is required for a bench top system there will be a charge.

The *Site Acceptance Test (SAT)* is an abbreviated FAT, done at the customer's site, to verify that the shipping process did not affect the skid system performance. This is a formal on-site testing conducted to demonstrate that the customized system meets the specifications and thereby the customer's acceptance criteria. We check the entire system step by step for functionality and safety. Every test step is documented in detail. The SAT is included in the standard instrumentation package price.

*Varian PreCare* is a time-based schedule of routine servicing of any instrument (bench top or skid) to prevent the failure of the system at an inopportune time. This is usually accomplished through a Varian PreCare Contract with the customer, after the original warranty has expired. The Service Contract is a stand-alone item, which can be added to any instrumentation package.

## Qualification Terminology

*Process Instrument Qualification (PIQ)* regulations have become more and more important and so it is imperative to understand the terminology used in the regulatory environment related to our P2P instruments (bench top or skid) and LC ReSponder™ software products. The qualification documents, and the actual on-site execution of the protocols, are sold as stand alone items for all systems and columns.

*Design Qualification (DQ)* is the process of documenting the instrument design. This document identifies all the Varian, Inc. supplied products within the design of the new instrumentation, and incorporates and identifies all the Original Equipment Manufacture (OEM) products that go into the product. This is a full system equipment description.

*Installation Qualification (IQ)* is the process of documenting and demonstrating that the installed instrument met the product design sold to the customer, as represented in the quotation. The IQ includes everything from checking the instrument shipment for damage to making sure that the user received all the modules and items that were purchased. This is a full system installation (set-up) document.

*Operational Qualification (OQ)* is the process of demonstrating that the complete instrument functions properly and meets the Varian stated specification. This is a full system functionality test.

*Performance Qualification (PQ)* is the procedure for demonstrating the system performance chromatographically, as a whole system, to ensure that it performs a good chromatographic/purification analysis of a standard compound. The PQ validation comprises evaluation of the combined system and column. The PQ is not a standard part of the Varian P2P qualification package and can only be done after defining the column and media needed by the customer, in a testing protocol. It is important not to confuse this PQ with the customer required process qualification test, which is often also referred to as the customer's PQ test. Varian does not participate in the customer's process qualification activities as they involve the customer's confidential process.

Varian, Inc.  
www.varianinc.com  
North America: 800.926.3000, 925.939.2400  
Europe The Netherlands: 31.118.67.1000  
Asia Pacific Australia: 613.9560.7133  
Latin America Brazil: 55.11.3238.0400

Other sales offices and dealers throughout the world—  
check our Web site.

