


Transval Version 1.0
FACTORY RELEASE FORM

Transval software provides calculations and reports dedicated to the transfer of Analytical methods. This is a product of:

ARLEND A

Rue de l'Hôpital 1, CHU Bat B36 - 4000 LIEGE 1 (Belgium)

Quality Product was managed by Qualilab and Arlenda (creation of a Validation Committee):

QUALILAB

1121, Rue de la Bergeresse - 45160 OLIVET (France)

An **Installation Qualification** demonstrated that Transval environment can be installed as described in the installation document (*TRANSV-10*) and that the server is able to satisfy Transval performance specifications.

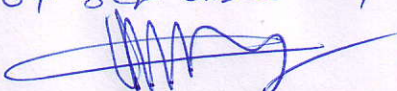
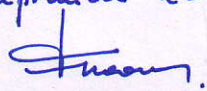
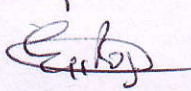
An **Operational qualification** was done using the validation environment, on 5 "Release candidate" versions: **Transval V 1.0 RC1 to Transval V 1.0 RC5**.

During these qualification tests,

- 35 low incidents were detected and closed
- 16 moderate incidents were detected and closed
- 7 critical incidents were detected and closed

A **Performance Qualification** was done using the production environment, on version: **Transval V 1.0 PROD**. This last Qualification demonstrated that the complete process of **Transval** (calculation, reporting, and environment) works well in its specified operating environment. Standard Operating Procedures were checked to ensure change control management and traceability, and availability of an up to date user's guide was also verified (1 low incident was detected and closed).

All these qualification results enable the Validation Committee to ensure that **Transval V 1.0 PROD can be released**.

<p>Eric CHAPUZET Quality Project Manager (QUALILAB)</p> <p style="font-size: small;">07 September 2007</p> 	<p>François MOONEN Project Manager (ARLEND A)</p> <p style="font-size: small;">10 September 2007</p> 	<p>Eric ROZET Quality assurance Manager (ARLEND A)</p> <p style="font-size: small;">10 September 2007</p> 
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