

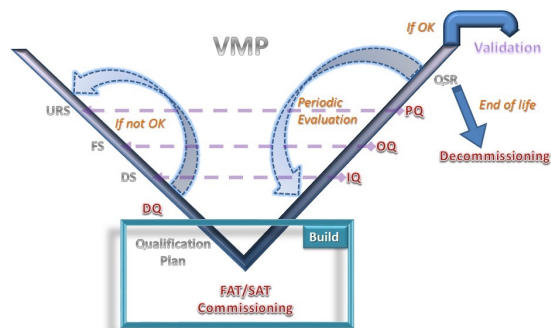


THE APPLICATION POINT

URS

URS = User Requirement Specification

The URS is a document that precisely defines **user requirements** and **expectations** for a product or service. It is a document that specifies the user's needs. The URS describes the **functionalities** and **performances** required by the user for the product, which must be taken into account during its **development**. It is **written by the product owner and end-users**, with the help of quality assurance, at the start of the validation process, generally before the product is conceived. These requirements are then **tested as part of the performance qualification (PQ)** process. For equipment purchased from catalogs, such as Interscience products, a URS is not mandatory. Since PQ is not carried out by Interscience, it is the customer's responsibility to check that the equipment he has purchased meets the requirements he has defined in his URS.



THE APPLICATION QUESTIONS

Question n°1 :

"What is the **maximum temperature** at which **SteriWater** filter tubing can be used ?"

SteriWater filter tubing are autoclavable up to 10 times and can resist **temperatures up to 140 °C**.

Question n°2 :

"What's the difference between the **calibration** and the **verification** of a **DiluFlow**?"

Calibration: Consists in **determining the accuracy of the instrument**. Calibration is carried out by taking a measurement with the instrument and comparing it with a **reference of known and certified value**, called a "**standard**". The value of the standard is obtained using measuring equipment calibrated by a recognized certification organization. In case of significant difference with the standard, the error is measured and corrected. Calibration must be carried out **regularly** to guarantee equipment performance.

Calibration of the DiluFlow Elite: Consists of measuring a **certified weight of 500 g** using the "**Calibration**" program (c.f. *user manual 4.3.11.5. Calibration*). If the **DiluFlow Elite** displays 500 g, then the device is correctly calibrated. If a difference is observed, then there is a measurement error and a correction must be applied, this is called **adjustment**.

Once the device has been calibrated, it must be verified before use.

Verification: Consists in **checking whether the instrument's measurement meets the manufacturer's requirements** under routine operating conditions. This ensures that the **device operates within acceptable limits** (defined by the **maximum tolerated error**). Verification is carried out by comparing the equipment's measurement with a **known reference value**, representative of the routine protocol applied. It is recommended that verification be carried out at least **once a day, before the equipment is used for the first time**.

Verification of the DiluFlow Elite: Consists of taking a measurement in "**Scale**" mode of a **known weight representative of the routine protocol** (c.f. *user manual 4.3.2. Getting started*). For example, in the food industry, with the **DiluFlow Elite 5 Kg**, verification can be carried out by measuring a 100 g weight. If the measurement obtained is equal to 100 g at ± 0.005 g (maximum tolerated error), then the measurement is acceptable. If not, recalibration is required.