

INSTALLATION AND OPERATIONAL QUALIFICATION OF QC INSTRUMENTS ON SITE

IQ/OQ provides assurance that consistent instrument quality and integrity are maintained

- INSTRUMENTS QUALIFICATION IS REQUIRED BY REGULATORY AUTHORITIES
- METICULOUSLY EXECUTED PROTOCOL DOCUMENTATION
- REDUCING IN-HOUSE VERIFICATION TIME
- PERFORMED WITH CALIBRATED MEASUREMENT INSTRUMENTS



National regulatory require documented verification that the QC instruments are installed and operated according to the manufacturer's intended use. Equipment IQ/OQ for 18F-FDG can be performed by Elysia-Raytest after instruments installation, modification or as a periodic requalification.

The **Installation Qualification procedure** (or IQ) confirms that the instrument is delivered and installed according to our strict specifications, which include identification of the system, product integrity documentation after shipment, verification of installation environment, check of instrument configuration and the presence of certificates and user manuals.

The **Operational Qualification** (or OQ) verifies and records the instrument's ability to meet specified performance criteria after installation. In the OQ report, each instrument is listed with its serial number and the corresponding measured performance to allow a fast and easy comparison with the instrument's specifications. Tests are performed with certified and calibrated tools (voltmeter, flow meter, thermometer...) by our trained-and-certified service engineers. The approved qualification report includes test results, raw data, instrument and engineer certificates, test protocols, qualification outline, record of key data (serial number of probes, batch number of reagents...);

Site requirements

Before installation, the customer will receive Elysia-Raytest IQ/OQ requirements that contain all the information needed to prepare for onsite qualification. Calibration radioactive sources have to be provided by the customer. The IQ/OQ analysis can only be performed if the customer fulfills the Elysia-raytest site requirements :

- Specific requirements for each instrument to be installed
- Calibration sources
- Chemicals (see specific site requirements)

Options

IQ/OQ for main FDG quality control equipment includes IQ/OQ for the following instruments:

- 1 radio-HPLC FDG
- 1 GC
- 1 TLC scanner
- 1 Dose calibrator
- 1 Gamma spectrometer
- 1 Endotoxin test
- 1 pH meter
- 1 MCA- gamma spectrometer



Additional equipment will be charged separately.

Elysia-Raytest can support the customer in his performance qualification or validation through customized separated offer.

