Establishment of production laboratory for Fluorodeoxyglucose ^{18}F (^{18}F-FDG)

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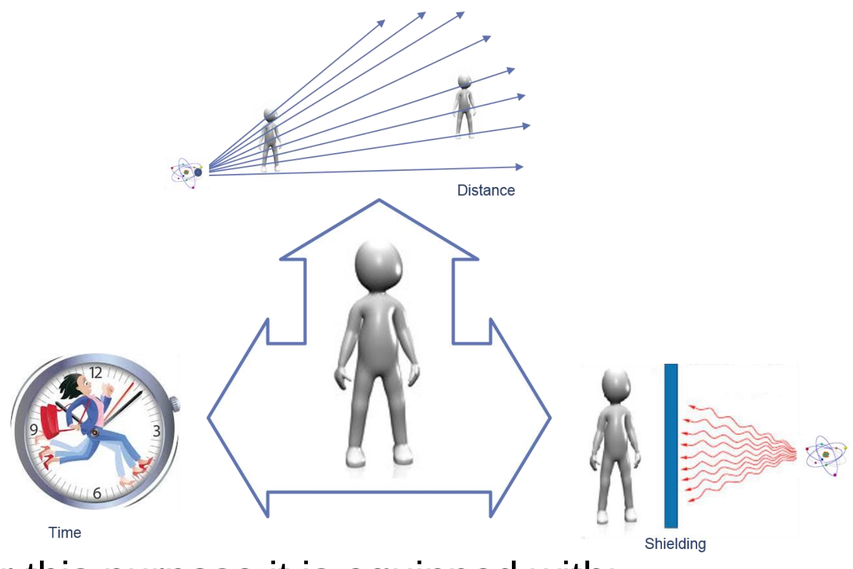
The radiopharmaceuticals such as ^{18}F-FDG are sterile radioactive products for human use and because that production procedure is subject to special requirements, that are achieved through administrative controls such as controlled access, segregation of work spaces and protocols written as standard operating procedures (SOPs), and through engineering controls such as interlocked doors, appropriate pressure gradients, an appropriate number of air changes and pass-through boxes. To minimize risks of radiation the production is fully automated in specially designed laboratories.

Three fundamental parameters that affect staff doses in the radiopharmacy:



The production of 18F-FDG should be carried out in clean areas and under negative pressure surrounded by a positive pressure zone ensuring that appropriate air quality requirements are met according EN ISO 14644-1.

Due to this requirements our laboratory is specially designed to ensure fully automated and safe production of ^{18}F-FDG, taking care of radiation protection and sterility - it is laboratory *of Class C, the room pressure is + 25 Pa, and the pressure in the hot cells is – 30 Pa.*

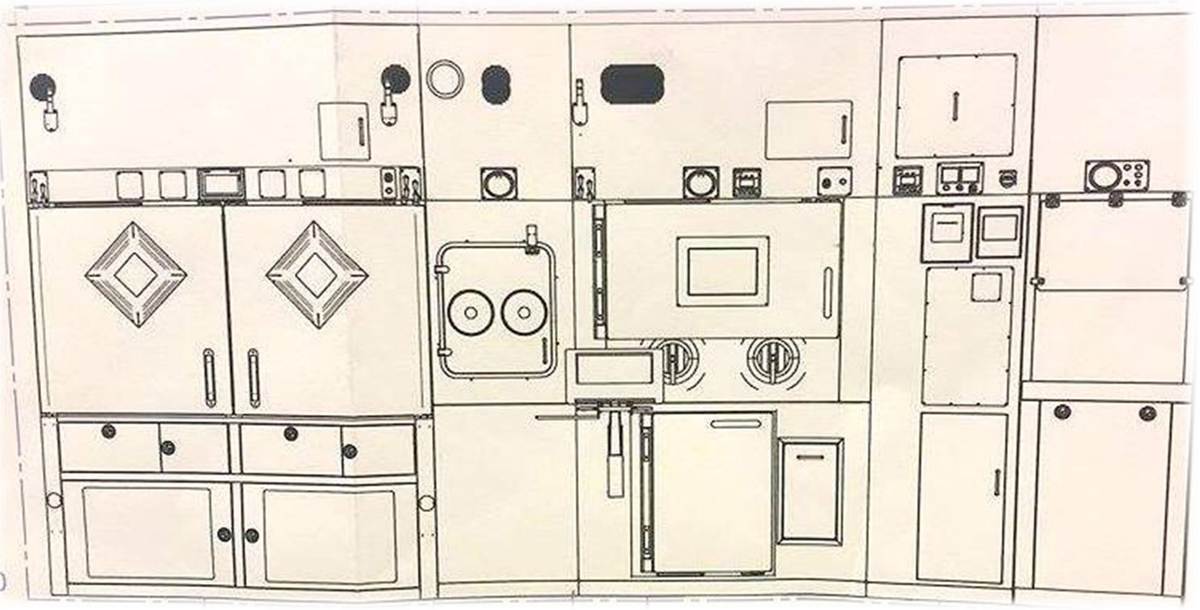
For this purpose it is equipped with:

- ✓ Double horizontal *BBS hot cell* shielded box (with two Synthera modules for ^{18}F-FDG synthesis)
- ✓ Hot cell for aseptic radiopharmaceutical dispensing *Talia* (equipped with a ventilation system that simultaneously ensures protection of the product and the operator.
- ✓ Class A laminar flow equipped with CLIO-automatic dispensing system)
- ✓ Laminar hood as a working area for preparation of cassettes for synthesis

Synthera module

Clio

BBS hot cells | **Talia hot cell** | **Laminar hood**



Smart Guard system - Environmental Radiation Monitoring System

The particle content in the air complies with the ISO 14644-1 and EEC-cGMP requisites.

To ensure the safe manufacture of ^{18}F-FDG radiopharmaceuticals, validation and qualification will be applied in accordance with the principles of ***Good Manufacturing Practices (GMP).***