ESTABLISHMENT OF PRODUCTION LABORATORY FOR FLUORODEOXYGLUCOSE 18F (18F-FDG)

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The radiopharmaceuticals such as ^{18}F-FDG are sterile radioactive products for human use and because of that production procedure is subject to special requirements. To minimize risks of radiation the production is fully automated in specially designed laboratories. On the other hand to minimize the microbiological and pyrogenic contamination during the production, all production steps should be carried out in clean areas entry to which should be through airlocks for personnel, equipment and materials. The production of ^{18}F-FDG should be carried out 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. For this purpose is equipped with double horizontal BBS1-SY hot cell shielded box designed to house automatic modules intended for routine production with two Synthera modules for ^{18}F-FDG synthesis, which are multi-purpose fully automated synthesizers . For dispensing of FDG we have hot cell for aseptic radiopharmaceutical dispensing Talia with Class A laminar flow equipped with CLIO - automatic dispensing system for radiopharmaceuticals, designed for dispense villas and syringes.

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). All personnel for production will be trained in GMP, the safe handling of radioactive materials and radiation safety procedures.

Key words: production, radiopharmaceuticals, hot cell, dispensing