

Question 1: How is the sterility of the PET products from the cyclotrons ensured and tested for? What is the time frame; the NRC inspectors were told 14 days during the inspection in May?

To ensure that the sterility of the final PET product is maintained the following activities take place:

- Use of sterile vials, syringes, needles, transfer sets, filters, etc.
- Use of sterile technique and sterile environment
- Daily cleaning of the Biological Safety Cabinet in the production Lab, and weekly cleaning of the Biological Safety Cabinet in the radiopharmacy lab
- Sterilizing filtration of the final PET product using a 0.22 µm sterile filter, and subsequent completion of the “Bubble Point Test” to test the integrity of the filter's sterilizing membrane.
- Microbiological testing of the final product by sterility and pyrogen tests initiated promptly.
 - Sterility samples submitted after 24 hrs, results obtained nominally in 8 days.
 - Pyrogen testing initiated immediately and completed on each batch of drug.

In addition, currently we are participating in the Clinical Center's USP monitoring program, which encompasses air sampling and surface sampling of the 2 areas that are used for sterile compounding. One location is the Biological Safety Cabinet in the PET production lab, and the other is the Biological Safety Cabinet in the PET radiopharmacy. This testing is currently done on a monthly basis.

Question 2: What procedures are in place for imaging of primates in the same rooms as humans are imaged to ensure protection of the patients and volunteers?

The following procedures are conducted:

- Before the animal enters the examination room, equipment not required for the study should be removed.
- The examination table or area will be draped with moisture-proof plastic sheeting and lined with absorbent material by the PET technologists.
- If surgical manipulation or blood drawing is necessary, areas which may come into contact with blood or other body fluids or potentially infectious materials will be draped and padded to prevent contamination.
- Cleaning supplies should be available for immediate use. Doors to the examination room will remain closed at all times. A sign stating “Special Study in Progress: Do Not Enter” will be placed outside the room. At the completion of the study, the room should be cleaned following the procedures used for “in isolation” patients. No patients will be allowed to enter the area until it has been cleaned. Post-study cleaning will be arranged through CC Housekeeping (5-3075) by PET staff immediately after the study. Linens and protective coverings, medical pathological waste, radioactive materials and i.v. infusion and blood sampling items used in the study must be removed and discarded.
- Patient care equipment which comes into direct contact with the animal (probes, transducer, restraint, etc.) must be sterilized before re-use. Steam, gas, or chemical sterilization should be used, as appropriate, for each item. Ideally this equipment should be duplicated whenever possible and labeled and stored separately from patient equipment.