Appendix III Components, Containers, and Closures Standards

1. Medical institutions must establish written procedures describing the receipt, login, identification, storage, handling, testing, and acceptance and/or rejection of components, drug product containers, closures, reagents, target materials, gases, transfer lines, purification device, membrane filter, analytical supplies (e.g. solvents, chromatography columns, and authentic standards), sterility test media, endotoxin test reagents, and other components. The procedures must be adequate to ensure that the components, containers, and closures are suitable for their intended use.
2. Medical institutions must establish written specifications for the identity, quality, and purity of components, and also for the identity and quality of components, drug product containers and closures.
3. Medical institutions must use a reliable supplier as a source of each lot of each component, container, and closure.
4. Medical institutions must uniquely identify and test or examine each lot of components and containers and closures. Except for the identity testing, other test items may be exempted based on the inspection report provided by the supplier.
5. Medical institutions must clearly distinguish the received components, containers, and closures based on the results of identification, testing or examination, and designated them as quarantined, accepted, or rejected.
6. The requirements for conducting identity testing on components, containers, and closures are as follows:
   6.1 For those medical institutions that conduct finished-product testing of a PET drug product：
      6.1.1 Which could ensure that the correct components have been used: Determine that each lot of components used in that

PET drug product complies with written specifications by examining a certificate of analysis provided by the supplier, which would not be required to perform a specific identity test on any of those components.

6.1.2 Which could not ensure that the correct components have been used: The identity testing of each component should be conducted.

6.2 For those medical institutions that do not conduct finished-product testing of a PET drug product：

6.2.1 Each component and added substance that yields active ingredients: It must be conducted identity testing.

6.2.2 For components other than paragraph 6.2.1 of this appendix (e.g. solvent and reagent):

6.2.2.1 Which are prepared as inactive ingredients: Medical institutions must perform identity testing on the components used to make the inactive ingredient before they are released for use. However, if using as an inactive ingredient a product that is marketed as a finished drug product intended for intravenous administration, they need not perform a specific identity test on that ingredient.

6.2.2.2 Which are not prepared as inactive ingredients: Medical institutions must determine that each lot complies with written specifications by examining a certificate of analysis provided by the supplier.

6.3 Except for visual identification, medical institutions must examine a representative sample of each lot of containers and closures for conformity to its written specifications.

7. Medical institutions must establish written procedures for confirming the integrity of the sterilized filter when using sterile

membrane filtration (0.22 μm) for final injection preparations and particulate filtration (0.45 μm) for final inhalation preparations of the PET drug products.

8. Medical institutions must establish written storage conditions (such as heat, light, humidity) to handle components, containers, and closures in a manner that ensures that they remain suitable for their intended use.

9. Medical institutions must keep a record for each lot of components, containers, and closures that received, which must include the identity and quantity of each shipment, the supplier's name and lot number, the date of receipt, the results of any testing performed, the disposition of rejected material, and the expiration date.

10. For components that are not designated expiration date, medical institutions should assign one based on knowledge of its physical and chemical properties and previous experience with its use; For organic substrates and reagents that are potentially susceptible to degradation or to a change in composition, the expiration date should be based on the material’s stability.

11. Medical institutions could not use components that do not meet specifications, expired or have not yet been released when compounding positron emission tomography drugs.