

Appendix V Laboratory Control Standards

1. Medical institutions must establish written procedures that each laboratory used to conduct testing of components, in-process materials, and finished PET drug products, and follow them for the conduct of each test and for the documentation of the results.
2. Each laboratory must have sampling and testing procedures designed to ensure that components, in-process materials, and PET drug products conform to appropriate standards, including established standards of identity, strength, quality, and purity.
3. Laboratory analytical methods must be suitable for their intended use and must be sufficiently sensitive, specific, accurate, and reproducible.
4. The identity, purity, and quality of reagents, solutions, and supplies used in testing procedures must be adequately controlled, and all self-prepared solutions must be properly labeled to show their identity and expiration date.
5. Each laboratory must have and follow written procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, and that these activities are documented.
6. Analytical instrumentation (such as gas chromatography or high-performance liquid chromatography) should be calibrated with internal or external standards after installation or major repairs to verify the applicability of the system.
7. Each laboratory performing tests related to the production of a PET drug must keep complete records of all tests, as follows:
 - 7.1 A suitable identification of the sample received for testing.
 - 7.2 A description of each method used in the testing of the sample, a record of all calculations performed in connection with each test, and a statement of the weight or measurement of the

- sample used for each test.
- 7.3 A complete record of all data obtained in the course of each test, including the date and time the test was conducted, and all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, in-process material, or drug product for each lot tested.
 - 7.4 A statement of the results of tests and how the results compare with established acceptance criteria.
 - 7.5 The initials or signature of the person performing the test and the date on which the test was performed.
8. Medical institutions must establish a written testing program to assess the stability characteristics of the PET drug products, and comply with the following provisions:
- 8.1 The samples tested for stability must be representative of the lot or batch from which they must be stored under suitable conditions.
 - 8.2 The results of such stability testing must be documented and kept.
 - 8.3 The results of such stability testing must be used in determining expiration dates and times and appropriate storage conditions, and ensuring that it still meets the specifications at the end of the expiration date for each PET drug product.
9. If changes in compounding procedures, computer programs, and component specifications are likely to affect the stability of the PET drug products, the stability should be reassessed.