Appendix IX Complaint Handling Standards

1. Medical institutions must develop and follow written procedures for handling of all complaints concerning the quality or purity of, or adverse reactions to, a PET drug product.
2. The complaint procedures must include review by a designated person and an investigation to determine the cause of the failure of a PET drug product to meet any of its specifications.
3. The acceptance, review and investigation of PET drug product complaints by medical institutions should be recorded and maintained.
4. The written record of each complaint should include the following information:
   - 4.1 The name, batch number and strength of the PET drug product.
   - 4.2 The name of the complainant and acceptor.
   - 4.3 The date the complaint was received.
   - 4.4 The nature of the complaint.
   - 4.5 The time and content of the response to the complaint, and the name of the replier.
   - 4.6 The findings of any investigation and follow-up.
5. A PET drug product that is returned because of a complaint or for any other reason may not be reprocessed and must be destroyed.