

Appendix X Records and Documentation Standards

1. Records and documentation must be maintained at the dispensing sites or another area that is reasonably accessible to responsible officials of the sites and to employees of the competent authority for health designated to perform inspections.
2. Medical institutions should properly identify all records and documentation of different editions and separately maintain them in the dispensing site to avoid misuse.
3. Medical institutions should clearly record all records and documentation which must be legible, stored to prevent deterioration or loss, and readily available for review and copying by employees of the competent authority for health.
4. Medical institutions must maintain all records and documentation for a period of at least three years from the date of final release, including conditional final release, of a PET drug product.