

6.2.4 Records shall be created and maintained to include:

- 1) Critical activities performed.
- 2) The individual who performed the activity.
- 3) When the activity was performed.
- 4) Results obtained.
- 5) Equipment used.
- 6) Critical materials used.
- 7) The facility where the activity was performed.

6.2.4.1 The system shall ensure that patient identifiers are unique.

6.2.5 Records shall be created concurrently with performance of each critical activity.

6.2.6 Changes to Records

Changes to records shall be controlled.

6.2.6.1 The date of changes and the identity of the individual who changed the record shall be documented, and this information shall be maintained for the retention period of the original record.

6.2.6.2 Record changes shall not obscure previously recorded information.

6.2.6.3 Changes to records (including electronic records) shall be verified for accuracy and completeness.

6.2.7 Electronic Records

There shall be processes and procedures to support the management of computer systems.

6.2.7.1 There shall be a process in place for routine backup of all critical data.

6.2.7.1.1 Procedures shall be in place to ensure that data are retrievable and usable.

6.2.7.1.2 Backup data shall be stored in an off-site location and be secured to prevent unauthorized access.

6.2.8 Storage of Records

Records shall be stored to:

- 1) Preserve record legibility and integrity for the entire retention period.
- 2) Protect from accidental or unauthorized access, destruction, or modification.
- 3) Allow retrieval.

6.2.9 Destruction of Records

Destruction of records shall be conducted in a manner that protects the confidential content of the records.

6.2A

Reference Standard 6.2A—Retention of Records

| Item No. | Standard | Record to Be Maintained | Minimum Retention Time (in years)^{1,2} |
|---------------------------------------|-----------------|---|--|
| General Quality System Records | | | |
| 1 | 1.2.2 | Management review of effectiveness of the quality system | 5 |
| 2 | 1.3.2 | Exceptions to policies, processes, and procedures | 10 |
| 3 | 1.4.1 | Emergency operation plan tested at defined intervals | 2 |
| 4 | 2.1 | Job descriptions | 5 |
| 5 | 2.1.1 | Qualification of personnel performing critical tasks | 5 |
| 6 | 2.1.2 | Training records of personnel | 5 |
| 7 | 2.1.3 | Evaluations of competence of personnel | 5 |
| 8 | 2.1.4 | Personnel records of each employee | 5 |
| 9 | 2.1.4.1 | Records of names, signatures, initials or identification codes, and inclusive dates of employment for authorized personnel who perform or review critical tasks | 10 |
| 10 | 3.2 | Equipment qualification | 10 after retirement of the equipment |
| 11 | 3.4 | Unique identification of equipment | 5 |
| 12 | 3.5 | Monitoring and maintenance of equipment | 10 after retirement of the equipment |
| 13 | 3.8 | Implementation and modification of software, hardware, or databases | 2 after retirement of the system |