
5. PROCESS CONTROL

5.0 Process Control

The perioperative program shall have policies and validated processes and procedures that ensure the quality of the components. The perioperative program shall ensure that these policies, processes, and procedures are carried out under controlled conditions.

5.1 General Elements



5.1.1 Change Control

The perioperative program shall have a process to develop and implement new processes and procedures or to change existing processes and procedures. This process shall include:

- 1) Identification of specifications.
- 2) Verification that specifications have been met.
- 3) Validation of new or changed processes and procedures before implementation.
- 4) Postimplementation assessment.

Standards 2.1.2 and 2.1.3 apply.

- 5.1.1.1** The perioperative program shall have a process to introduce new or novel uses of existing or new perioperative methods and components.



5.1.2 Quality Control

A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment, and methods function as expected. Testing shall be performed at defined intervals. Quality control results shall be reviewed and corrective action taken when appropriate.

5.1.2.1 Quality control results shall be reviewed and evaluated against acceptance criteria. Quality control failures shall be investigated. Standard 8.2, #5 applies.

5.1.2.2 The validity of test results and methods and the acceptability of components or services provided shall be evaluated when quality control failures occur.

5.1.3 Use of Materials

All materials that are used to collect, prepare, process, test, store, or administer components shall be used in accordance with the manufacturers' instructions for use and shall meet specified requirements.



5.1.4 Facility-Prepared Pharmaceuticals, Solutions, and Reagents

The facility shall have defined criteria for pharmaceuticals, solutions, and reagents that are prepared in-house.

5.1.5 Prevention of Contamination

The perioperative program shall employ methods that provide assurance of a pyrogen-free product. Standard 5.3.1 applies. Single-use materials, sterile, and pyrogen-free pharmaceuticals, solutions, and reagents shall be used.

5.1.5.1 Single-patient-use materials intended to produce a postoperative component shall be used for no more than 24 hours after coming into contact with a patient's blood at room temperature. Standard 1.3.1; Reference Standard 5.1.8A, Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Com-

ponents; Reference Standard 5.1.8B, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion; and Reference Standard 5.1.8C, Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application apply.

5.1.5.2 The perioperative program shall define the length of time disposables may be opened and set up before use. Timeframes shall be consistent with manufacturer's instructions for use.

5.1.6 Identification and Traceability

The perioperative program shall ensure that all components and critical materials used in their processing, as well as laboratory samples and patient records, are identified and traceable.



5.1.6.1 Process or Procedure Steps

The perioperative program shall have a process to identify the individuals performing each critical step in collection, processing, and administration of components and when each step was performed. Standard 6.2.4 applies.

5.1.6.2 General Labeling Requirements

The perioperative program shall have a labeling process for components, including review of patient identification before the label is applied. This process shall include steps taken to:

- 1) Identify the collection container, components, samples, and modified components.
- 2) Complete the required reviews.
- 3) Attach the appropriate labels.