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.

G u i d a n c e

"Process control" refers to the management of processes and procedures that affect the quality of products and services. Process control ensures that processes and procedures will be performed consistently and as they were intended to be performed. The program activities will include some or all of the following: collection, preparation, processing, storage, administration, or disposal. To manage these processes and procedures*, the program* will develop and document processes and procedures for those activities that directly affect the quality of perioperative components. In most programs, these processes and procedures will already exist, but they have to be identified and documented. When all processes and procedures conform to established requirements, their output should result in acceptable components and services.

Implicit in general process control are the following concepts:

Critical processes in the collection, storage, preparation, processing, or reinfusion of components should be validated (tested to ensure that the process consistently delivers perioperative components that meet previously defined requirements) before their initial use and after modification or change. There must be a defined mechanism to ensure that validation of new or changed processes occurs.

To implement process control, programs may consider the following guidelines:

1. Identify the processes and procedures that need to be followed to fulfill the requirements for perioperative components.
2. Capture all processes and procedures in writing, as required in Standard 1.3.
3. Before implementation, validate all new processes and procedures to ensure they function as designed and meet or exceed the outcome(s) intended. An example of a validation method would be running saline through a blood recovery device to validate a new computer program driver controls that all the pumps and valves work as expected before using outdated blood components to validate that the new program produces component acceptable to manufacturer's specifications and performs according to facility's acceptance criteria.
4. Review and approve processes and procedures, as required in Chapter 6, Documents and Records.
5. Train staff to comply with processes and procedures, as required in Chapter 2, Resources.
6. Validation requirements specific for equipment are outlined in Chapter 3, Equipment.

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.

Guidance

Standard 5.1.1 requires change control documentation and validation of new or changed processes and procedures before implementation. When developing a new process, participation by representatives from all of the involved departments and work areas ensures that the planned activities fit and work within each environment. The same departments and work areas should participate in the validation. A validation plan should include documentation of the following:

- Installation Qualification (IQ)/ Initial Design Verification.
- Operational Qualification (OQ)/ Initial Design Validation.
- Performance Qualification (PQ)/ Design Validation.
- Implementation Plan.

After implementation a Postimplementation Assessment should be documented with Process Improvements and/ or Process Control/ Quality Control monitoring parameters if appropriate. Validation confirms both of the following:

- The design allows the work to be performed consistently to achieve the intended results.
- The work instructions are clear, complete, and easy to use.

Even when validation has been performed carefully, it is still possible to find errors and omissions after implementation. If errors occur, authorized and controlled changes to the way work is performed and to the corresponding processes and procedures, need to be made without delay and monitored for effective process control.

The intent of Standard 5.1.1 is not for programs to perform validation on processes and procedures that have been in place for years. For these processes and procedures, retrospective validation is acceptable, which could include a review of historical records, which serve as the documented evidence of a controlled process or procedure. For example, if a program has been performing blood recovery for many years, the program's procedure and quality control records can provide evidence that the expected results are consistently achieved. It is recommended that the program have a statement on file to this effect to serve as the record of validation. It should be noted, however, if problems in current processes and procedures have been identified, or if there is no active mechanism to identify problems, validation of all processes and procedures in Chapter 5 is recommended.

Processes and procedures are required to be controlled because they relate most directly to the quality of the perioperative components. When processes and procedures are validated, and competent trained staff perform them the same way each time, the program can be confident that the controlled conditions will consistently result in the intended perioperative component.

Because *Perioperative Standards* represents minimum requirements, programs are encouraged to implement additional measures that are appropriate for their program. For example, programs should consider validating safety processes; documenting control processes, ensuing that the event reporting process works; or that the competency assessment, internal audit tool, or any written procedure can be understood and executed.

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.

Guidance

The perioperative program must have in place a program of quality control to ensure that reagents, personnel, equipment, and processes function as expected. The scope of the program can vary based on the medical device and the manufacturer's recommendations; however, it must be defined by each perioperative program. At a minimum the perioperative program should monitor the effectiveness of the operator and device and the quality of materials used and produced. Quality control could include correlation with patient's condition regarding appropriate use of components and/ or chart review of documentation requirements. Records of these reviews must be maintained.

The purpose of a quality control program for perioperative collection activities is to ensure that a perioperative component of consistent quality is made. In general, perioperative activities that simply collect and reinfuse whole blood or recovered blood without modification (other than simple filtration) are difficult to assess by testing because patient characteristics determine the nature of the end product; appropriate patient selection and adherence to procedural techniques/controls are critical in ensuring a quality perioperative component. If the collected material is altered by some procedure, then periodic measurements of component's quality are useful to monitor ongoing processes. All perioperative components should be measured for volume and appropriately labeled. The final quality assessment should include visual inspection at the end of processing and before administration.

The quality control program should specify the type and frequency of testing, and the tolerance limits for each assay or test performed. For example, a perioperative program that performs only red cell recovery may elect to test one red cell component collected on each device in use once per month. Hematocrit may be the defined routine testing, with established acceptance range of 40-60%. (The acceptance range, though, should be determined by the institution or based on the manufacturer's specifications because it can vary with type of instrument used, analyzer or method used to measure the hematocrit, as well as other variables.) The hematocrit results should be reviewed and assessed by acceptance criteria defined. For example, the hematocrit values can be charted per device over time to demonstrate continuous process control to investigate trends and failures. Any failures should have documented investigation as well as chart review of the recipient's chart for possible adverse event. A root cause analysis may reveal the cause to be a partially filled bowl, inadequate pump speeds, dirty optics, excessive hemolysis or premature wash cycle, unexpected events during the surgical case, operator error, or the need for recalibration and revalidation of the device before use for a patient. Depending on the cause of the outlier, the corrective action may be to perform more frequent quality control testing or possibly additional testing of components made from that particular device to ensure the consistency of the components produced. Effective quality monitoring should identify problems early to prevent possible harm to the patient.