2.0 Quality Assurance Policies

Contact Information:

Quality Assurance Department

Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Phone: (817) 412-5580
Fax: (817) 412-5659

Carter BloodCare
815 South Baxter Avenue
Tyler, TX 75701
Phone: (903) 363-0419
Fax: (903) 363-0467

Email to submit completed notification forms: QANotifications@carterbloodcare.org

2.1 Quality Policy Statement

The Quality Policy of Carter BloodCare is to provide safe and efficacious blood and blood components in a manner that meets or exceeds the expectations of our internal and external customers.

Carter BloodCare maintains a quality management system to meet or exceed the minimum requirements of the Food and Drug Administration, AABB, and other accrediting organizations. Quality system essentials are defined in the Quality Plan. Quality Plan changes reflect the results of self-assessment activities, increasing maturity of the Quality Plan, organizational changes, and technical development.

Quality processes, products, and people are the foundation upon which the quality management system of Carter BloodCare is built. The quality management system supports the ideals set forth in the quality policy statement of Carter BloodCare. The quality management system monitors processes and operations by self-assessment audits, error management, and customer feedback. By conforming to regulatory standards, Carter BloodCare abides by the law. By conforming to requirements for accreditation, Carter BloodCare adheres to the high standards for quality established by AABB and other peer-review organizations. By conforming to our customers' needs, Carter BloodCare practices the philosophy of continuous quality improvement.

2.2 Quarantine Notices

The Food and Drug Administration and AABB have recommended the quarantine of previously donated blood components from donors currently testing repeatedly reactive for infectious disease markers, reactive for HCV-NAT (nucleic acid testing), HIV-1-NAT, HBV-NAT, WNV-NAT, Chagas' disease, and for donors responding affirmatively to being at risk for Creutzfeldt-Jakob Disease (CJD) or vCJD. In-date blood components, meeting criteria as defined by FDA and AABB, are to be quarantined and returned to Carter BloodCare. In the event that a donation meets any of these criteria, you will be notified by a Quarantine Notice.

A Quarantine Notice may also be sent if a donor reports post-donation information that may affect the safety of the unit. Components are to be quarantined and returned to Carter BloodCare until our medical staff can evaluate the medical and regulatory implications of the information. The final component disposition of implicated components is determined on a case-by-case basis. Although most components will be discarded upon return, it is possible that further evaluation of the callback information may determine the component is acceptable for release back into regular inventory. This notice may be initiated by the Quality Assurance, Reference & Transfusion, Distribution, or Records Audit and Data Entry departments.

If your facility received blood components requiring lookback or recall notification, the Quality Assurance department will notify your facility. The Quarantine Notice (see example forms at the end of this section) will be addressed to the primary contact or the facility head.

If you receive a Quarantine Notice:

1) Immediately determine if the blood component is in your inventory.
2) If the blood component is in your inventory, the component should immediately be quarantined for return. Please call the Distribution department for blood component pick-up. **There is no charge to your facility for this pick-up.** Complete the appropriate section of the Quarantine Notice and fax it as soon as possible to the Quality Assurance department.
3) If the blood component is not in your inventory, complete the appropriate section of the Quarantine Notice and fax or email it as soon as possible to the Quality Assurance department.

If the completed Quarantine Notice is not received by the Quality Assurance department within approximately four (4) weeks, a second notice will be sent to the facility.

Quarantine notification is considered to be closed after written disposition of the blood component is received by the Quality Assurance department on the returned Quarantine Notice form or after the second notice is sent to the facility.

For additional information regarding quarantine notification, please contact the Quality Assurance department.

2.2.1 Quarantine/Lookback Notices

The Food and Drug Administration and the AABB have recommended lookback notification on previously donated blood components from donors who have subsequently tested confirmed positive for HIV,HCV or Chagas' by confirmatory or supplemental testing.

If your facility has received blood components implicated in a lookback investigation, the Transfusion Service Medical Director or the facility head will receive a Quarantine Notice with subsequent confirmatory test results as a certified letter detailing the reason for lookback. Each facility should determine what action to take when implicated blood components have been transfused. The FDA and HCFA have published information regarding these lookback investigation requirements.

For additional information regarding lookback notification, please contact the Quality Assurance department.

2.3 Recall/Market Withdrawal Notices

Recall/market withdrawal is a method for removing components from inventory that do not meet the requirements of the Food and Drug Administration, AABB, or Carter BloodCare. Reasons for recall/market withdrawal include, but are not limited to:

Manufacturer-directed withdrawal (e.g. phlebotomy bag withdrawn by manufacturer)

Variance from Carter BloodCare's Standard Operating Procedures

Recall/market withdrawal from an outside blood center for an imported product.

If the involved blood component is in-date, the receiving facility will be notified and requested to immediately quarantine and return the blood component.

If your facility received and used an involved blood component, the Transfusion Service Medical Director or the facility head will be faxed a notice detailing the reason for retrieval and the blood components involved. A Component Recall/Market Withdrawal form (see example forms in this section) will be included for your facility to complete and return by fax or email to the Quality Assurance department.

Each facility should determine what steps to take when a recalled blood component has been transfused.

For additional information regarding Recall/Market Withdrawal notices, please contact the Quality Assurance department.

2.4 Quality Assurance Consultation Services

The Carter BloodCare Quality Assurance department staff is available to provide information to answer questions on FDA and AABB requirements for Transfusion Services. Additionally, the Quality Assurance department can assist you in the development of your Quality Plan.

Carter BloodCare license information and component quality control summary data are available for your review upon request.

Please contact the Quality Assurance department or the Hospital Relations department for more information.

2.5 Forms

DPF400.20A Quarantine Request Facsimile
DPF400.20B Quarantine Release Request Facsimile
QAF403.01 Suspected Component Contamination Notification
QAF601.01A Component Recall Market Withdrawal Notification
QAF601.01B Quarantine-Release Notification
QAF602.01 Consignee Notification Record
QAF602.01.01 Reac Non-Descrim Multiplex HIV-1--HCV Assay Notification
RAF601.00 Request for Product Quarantine RADE
RTF120.11A Request for Product Quarantine, Discard or Retrieval
RTF120.11D Reference & Transfusion Suspected Component Contamination Notification