Quality Review for Prehospital Transfusion Clients

Site Name: _____

Address: _____

Site Contact Person: _____ **Phone:** _____

Email: _____ **Date:** _____

1. **Qualification (AABB Std. 2.1.2)** Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training and/or experience.

Provide documentation that training has occurred for all personnel handling blood and blood components and responding to temperature excursions.	Evidence provided, reviewed and deemed acceptable? ☐ Yes ☐ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

2. Qualification of Equipment (AABB Std. 3.2) All critical equipment shall be qualified for its intended use. Equipment shall be requalified, as needed, after repairs and upgrades.

Equipment Monitoring and Maintenance (Std. 3.5) Equipment shall be monitored and maintained in accordance with the manufacture's written instructions. Provide evidence for the review of temperature logs, onboard storage devices, alarm system, etc.	Evidence provided, reviewed and deemed acceptable? ☐ Yes ☐ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

Calibration and Accuracy of Equipment (Std. 3.5.2) When equipment is found to be out of calibration or specification, the validity of previous inspection and tests results and the conformance of potentially affected products shall be verified. Issues regarding equipment out of specifications were documented, investigated, and resolved.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

Equipment Cleanliness (Std. 3.5.3) Define cleaning and sanitization methods and intervals for equipment. Provide evidence of cleaning and sanitization methods and intervals.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

Equipment Removed from Service (Std. 3.5.3) Remove equipment from service that is malfunctioning/ out of service and communicate to appropriate personnel. Provide evidence regarding how the facility removes non-functioning equipment from service and communicates that to the appropriate personnel.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

Returning Equipment to Service (Std. 3.5.4) Investigation and follow-up of equipment malfunctions and failures are required. Provide evidence of requalification of malfunctioning equipment and return to service.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

3. Storage and Transport Devices for Blood and Blood Components (AABB Std 3.8) Storage and Transport devices shall have the capacity and design to ensure that the proper temperature is maintained.

Returning Equipment to Service (Std. 3.8.1) Storage devices shall be set to activate under conditions that will allow enough time for proper action to be taken before products reach unacceptable conditions. Provide samples of temperature and alarm activation records. Review monitoring systems, alarms or graphs to see evidence of action taken when alarms occur.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

4. Process Control (AABB Std. 5.0) The organization shall ensure the quality of products and services.

Final Disposition (Std. 5.1.8.3) The TAS shall be responsible for recording the final disposition of blood or blood components. Explain how you track the final disposition of blood and blood components.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

Blood Storage Temperature Monitoring (Std. 5.1.9.3) For storage of blood and blood components, the temperature shall be monitored continuously and recorded at least every 4 hours. Describe the temperature monitoring system. Are temperatures of storage devices for blood products monitored continuously or recorded at least every 4 hours? Review charts or monitoring system to ensure evidence support proper storage conditions.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

5. Deviations, Nonconformances, and Adverse Events (AABB Std. 7.0) The organization shall capture assess, investigate, and monitor failures to meet specified requirements. The responsibility for review and authority for the disposition of nonconformance's shall be defined. These events shall be reported in accordance with specified requirements and to outside agencies as required.

Nonconformances (Std. 7.2.1) Upon discovery, nonconforming products shall be evaluated and their disposition determined. Provide evidence of a process for evaluating and determining disposition of products.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

Look-Back (Std. 7.3.5) The TAS shall have a process for providing relevant unit and/or patient information as requested when notified by the blood collection facility and/or transfusion service. Provide information on your process to provide relevant unit and patient information to a requested collection or transfusion service.	Evidence provided, reviewed and deemed acceptable? □ Yes □ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

6. Internal and External Assessment (AABB QSE 8)

Blood Utilization and Wastage (QSE 8.5) Provide information on your process for monitoring blood utilization and wastage.	Evidence provided, reviewed and deemed acceptable? ☐ Yes ☐ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

7. Facilities and Safety (AABB QSE 10)

Handling and Discarding Biological Materials (QSE 10.3) Provide information on your process on discarding biological materials that minimize the potential for human exposure to infectious agents.	Evidence provided, reviewed and deemed acceptable? ☐ Yes ☐ No (if no, explain below)
Comments: Dates of documents reviewed (if applicable) _____- _____	

Quality Review Acceptable? ☐ Yes ☐ No (If no, reschedule Quality Re-Review date: _____)

PMQC designee signature: _____ Date: _____

Facility Representative signature: _____ Date: _____

Based on the information stated in this review, Quality Assurance agrees that the above-listed facility has provided clear evidence that the blood products in their stewardship are managed appropriately to maintain their purity, potency, and safety.

QA Designee: _____ Date: _____