TRAINING UPDATE

Lab Location:	GEC	**Date Implemented:**	10.26.12
Department:	Blood Bank	**Due Date:**	11.30.12

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Blood Bank Quality Plan
Description of change(s):
Previously stated: Records are maintained at SGBB. **Changed to: Records are stored at GEC for 2 years and then moved offsite for the remainder of the storage period.**

EMPLOYEE SIGNATURES

Employee signatures are not necessary. Please document that you read and understand this updated procedure by taking the quiz in MTS.

Non-Technical SOP

Title	**Blood Bank Quality Plan**	
Prepared by	Leslie Barrett	Date: 1/22/2009
Owner	Stephanie Codina	Date: 10/22/2012

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

12 month (or new) management review and approval: **Signature acknowledges SOP version remains in effect with NO revisions.**		
Print Name	**Signature**	**Date**

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1. PURPOSE

To define a quality system that monitors the processes and operations of the blood bank functions performed at the Germantown Emergency Center laboratory.

2. SCOPE

This procedure applies to all applicable blood bank functions performed at the Germantown Emergency Center laboratory.

3. RESPONSIBILITY

The Blood Bank Manager/Supervisor is responsible for this procedure.

4. DEFINITIONS

SGBB – Shady Grove Adventist Hospital blood bank
GEC – Germantown laboratory at the emergent care facility

5. PROCEDURE

Responsible Party	Activity	Applicable Document
BB Supervisor/ Manager	1. Determines the operating systems that function in this facility 2. Presents summary of requirements at the Lab Performance Improvement Committee (LPIC).	
Medical Director PI Committee	Approves content of Quality Plan	LPIC meeting minutes
BB Supervisor/ Manager	Drafts Quality Plan to cover all quality system essentials / operating systems	Quality Plan draft

Medical Director	Approves content and text of Quality Plan	Quality Plan
BB Supervisor/ Manager Staff	1. Ensures that self-assessments and internal audits are conducted as scheduled 2. Monitors inspection reports / occurrences / customer feedback for trends and effect of corrective action; prepares summary report for PI meeting	1. Audit checklists 2. Data collection forms 3. Inspection reports 4. Occurrence reports 5. QA reports
PI Committee	Reviews self-assessments for the operating systems	LPIC meeting minutes

6. RELATED DOCUMENTS

None

7. REFERENCES

- Standards for blood banks and transfusion services, 28th ed. Bethesda, MD: AABB, 2012.
- The quality program. Bethesda, MD: American Association of Blood Banks, 1994.
- Transfusion medicine checklist. Northfield, IL: College of American Pathologists, Sept 2007.

8. REVISION HISTORY

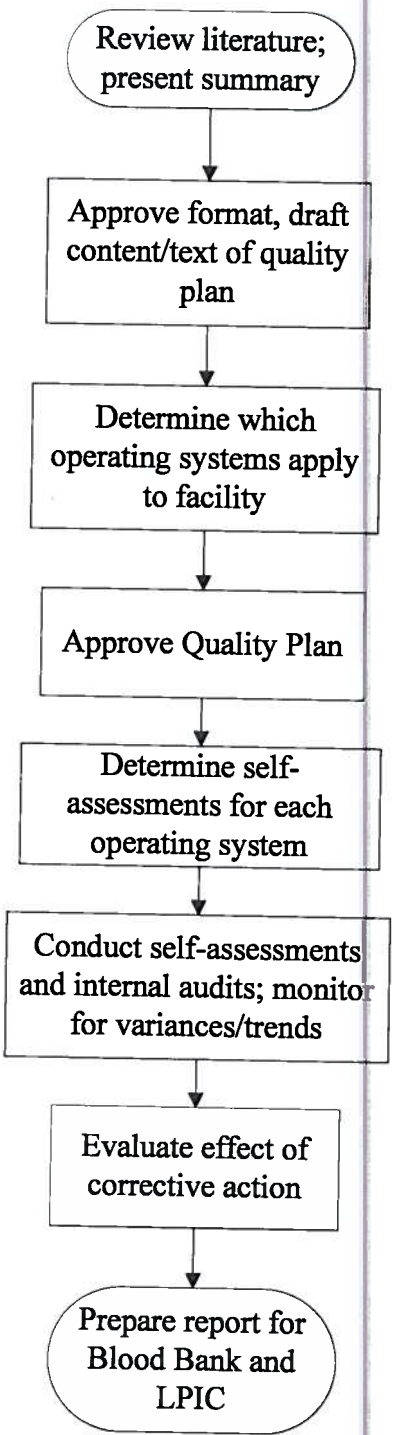
Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP GECB004.000		
000	6/5/2009	Addenda B: added monthly QC review	M. Hall	Dr Cacciabeve
001	10.22.12	Update owner Addenda B: Updated location of stored documents.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

A. Flowchart
B. Operating Systems

Attachment A

DESIGN AND REVIEW OF THE QUALITY PROGRAM



Attachment B

OPERATING SYSTEMS FOR GEC

A. Personnel – Selection, Training and Competence
   1. Job descriptions and employee qualifications
      - Job descriptions are written and maintained for each position.
      - To be considered for hire, candidates must meet the qualifications (education and/or experience) stated in the job description.
      - The candidate must provide documentation of education, training, and experience.
   2. Orientation
      - New employees are provided orientation to the organization, department, and specific job for which they are hired.
   3. Training
      - Training is provided as required per job description expectations and includes training related to specific job requirements, safety, computer, personal development, quality, and other skills as needed.
      - Staff development is provided to meet individual needs, regulatory and accreditation requirements, and the changing needs of the facility.
      - Training is considered completed when the individual demonstrates sufficient knowledge and skills for the job task.
      - Retraining is initiated when indicated.
      - Documentation of training and initial competence is maintained.
   4. Assessment of competence
      - Staff competence is initially determined during job task training.
      - Ongoing competence is assessed after six months and at least annually thereafter.
      - Documentation of competence assessment is maintained
   5. Continuing education
      - Continuing education by the various means available (hospital based center of organizational learning, seminars, workshops, teleconferences, journal review, etc.) is encouraged.
      - Documentation of continuing education is maintained.
   6. Performance appraisal
      - A performance review based on job accountabilities, objective measures, and pre-defined standards is completed for each employee, documented, and maintained.
   7. Trainer qualification
      - Training is provided by SGBB staff.
      - GEC staff who meet qualifications may function as trainers in this facility.

B. Equipment
   1. Selection and Installation
      - This process resides within the SGBB Quality Plan and is performed by SGBB staff.
   2. Calibration
      - All measurement devices, new or repaired, used in critical processes are calibrated according to procedures written in accordance with manufacturer's recommendations, regulatory requirements, and accreditation standards.

- The thermometer and recording thermometer of the blood storage refrigerator are calibrated annually by GEC laboratory staff with SGBB assistance.
- Complete documentation of equipment identity, results of scheduled calibrations, actions taken, and disposition of the equipment, is maintained.

4. Preventive Maintenance
   - Preventive maintenance schedules are determined by the manufacturer's recommendations, regulatory requirements, accreditation standards, and internal requirements.
   - Documentation of maintenance includes findings, actions, and follows up by GEC laboratory staff with SGBB staff assistance.
5. Defective Equipment
   - Defective equipment is identified, controlled, and repaired or replaced.

C. Supplier Issues
1. Supplier qualifications reside within the SGBB Quality Plan
2. Critical Equipment, Supplies and Services are limited to:
   - Blood storage refrigerator
   - Red blood cells provided by SGBB
   - Rh immune globulin provided by SGBB

D. Process Control - Labels, Quality Control
1. Standard operating procedures
   - Written procedures and policies for operations tasks are prepared within the scope of the SGBB Quality Plan
   - Procedures include handling, storage, distribution, and transport of blood / blood products and actions for non-conforming blood / blood products.
   - Procedures include criteria for the release of blood or blood products.
   - The process to change established processes and/or procedures resides within the scope of the SGBB Quality Plan. Such changes are documented and approved.
2. Process validation
   - Validation activities are contained within the scope of the SGBB Quality Plan.
3. Label control
   - The only label utilized is 'Warning, Uncross matched Blood' label.
   - This label is provided by SGBB and covered within the SGBB Quality Plan.
4. Quality control
   - The established schedule for QC of the blood storage refrigerator –
     - Daily temperature and visual appearance of blood documented
     - Continuous temperature recording chart replaced weekly
     - Alarm check performed quarterly
     - QC summary reviewed by Pathologist monthly

E. Document and Record Management
1. Documents are prepared and retained within the scope of the SGBB Quality Plan
2. Records are maintained on site for at least 2 years. After 2 years, the records are either sent to SGBB or offsite for storage.

F. Incidents, Errors and Accidents
1. The SGBB Quality Plan and Laboratory PI Plan contains a system to document and investigate events via the Performance Improvement Variance form.
2. Occurrences at GEC are handled within the above plans.

G. Assessments and Process Improvement
1. External assessments
   - GEC participates in external assessments conducted by the FDA, HCFA, and State, where required.
   - SGBB participates in the voluntary external assessments required of accreditation programs (JCAHO, CAP, and AABB.) Blood bank activities at GEC are assessed within this scope. A process is maintained to conduct, report, and follow-up on external inspections, assessments, or investigations
2. Operational self-assessments
   - Planned audits are incorporated within the SGBB Quality Plan
   - The applicable operating systems are –
     - storage, transportation, and expiration
     - blood bank and transfusion service records
3. Process improvement
   - Activities follow the SGBB Quality Plan and Laboratory PI Plan
   - Sources for improvement include –
     - external assessment report findings (FDA, JCAHO, AABB, CAP)
     - the findings from quality indicators of operating systems and internal quality audits
     - reports of customer complaints
     - analysis of incident, error, accident reports
     - review of any selected process to determine if the process can be made more efficient and effective

H. Facilities and Safety
1. As part of the hospital mandated environmental control program, procedures are maintained and training is provided for:
   - emergency preparedness
   - chemical hygiene ("right to know")
   - blood borne pathogens
   - general safety
2. Annual training and competency is documented via the hospital Learning Suite program.