TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	3/7/2019
Department:	Mgmt & QA	**Due Date:**	3/31/2019
		Implementation:	**3/12/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Document Control SGAH.QA05 v13

Description of change(s):

Header: updated facility

Section 4: added MediaLab and associated terms

Section 5: added ML transition process, change review checklist to optional

Section 6: added ML SOP

Section 9: updated all to match ML processes

This revised SOP will be implemented on March 12, 2019

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**Document Control**	
Prepared by	Leslie Barrett	Date: 3/20/2009
Owner	Cynthia Bowman-Gholston	Date: 3/20/2009

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:	

Review:		
Print Name	**Signature**	**Date**

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TABLE OF CONTENTS

1. PURPOSE

This procedure outlines the process for document control.

2. SCOPE

The document control system includes all procedures, policies and forms utilized by the Laboratory. It assures that:

1. all copies of policies and procedures are current;
2. personnel have read the policies/procedures relevant to their job activities;
3. all policies/procedures have been authorized by the medical director before implementation;
4. policies and procedures are reviewed periodically by the medical director or designee;
5. discontinued policies/procedures are quarantined in a separate electronic file for the appropriate retention period

3. RESPONSIBILITY

The section supervisor is responsible for keeping the SOP's current and reviewed.

The medical director is responsible for approving all new or revised SOP's. The medical director may delegate signature authority to the appropriate supervisor for periodic review if no changes are made.

In event of a change in directorship of the laboratory, it is the responsibility of the new director to review all procedures within a reasonable period of time, but within one year.

The supervisor must ensure employees review all pertinent procedures:

- prior to completion of the training/competency period
- when revisions are implemented

4. DEFINITIONS

SmartSolve® – (also referred to as SS or Pilgrim) software application previously used for electronic document control system (EDCS); transition to a new system began January 1, 2019

MediaLab – software application for electronic document control system (EDCS); may be referred to as ML

'Owner' as described on page 1 in the SOP – Person responsible for drafting or delegating the drafting of initial SOP. Person is responsible for the output of the SOP and ensuring that the SOP is current and reviewed periodically, usually a director, manager or supervisor.

Primary Site Administrator or additional Site Administrators – Person who is responsible for maintaining documents on the system, by processing new, revised, periodic review, and expiring SOPs.

Approver – Person who has been included on one or more document approval routes. Often the 'Owner' as described on page 1 in the SOP. Responsible for reviewing, approving, or rejecting a document.

Designated Reviewers – The owners of documents in the system, usually assigned to supervisor of the section / department. They will receive the recurring review email 90 days in advance of that review being due.

Controlled Copy – Printed copy of a document has a unique copy ID number, which allows it to be tracked and managed. When a controlled copy is created, its location is entered, so that is may later be found if it needs to be replaced.

Uncontrolled Copy – Copy of a document that is not managed through document control. It does not have a unique number or set location and must be shredded by the end of the shift.

Periodic Review - All SOPs must be reviewed and reapproved by the appropriately designated and licensed department director on a periodic basis not to exceed 24 months from the previous reviewed date.

System SOP – A procedure utilized by multiple laboratory sites (specified in SOP header).

Site Specific SOP – A procedure utilized by one laboratory site, specified in SOP header and numbering sequence.

5. PROCEDURE

1. Documents are maintained on an electronic system. As of January 1, 2019 migration to the MediaLab document system began. During the transition process, some documents are maintained in SmartSolve® document system. As documents are moved into MediaLab, the prior documents are retired from SmartSolve®.
   - Designated Document Managers have access rights to edit data/files and create/track approvals.
   - Approvers have the ability to approve, view and print documents.
   - Designated staff has access to read or print only.

2. The processes for new, revised or periodic review of documents are detailed in attachments A, B and C at the end of this procedure.

3. System SOPs are numbered with a prefix for Shady Grove Medical Center (SGAH for SOPs transitioned from SS, SGMC for new SOPs added to ML) and all applicable laboratory sites are listed in the SOP header.

4. When preparing a new procedure, the SOP Review checklist may be completed and submitted with the procedure.

5. Periodic review
   a. Periodic review is documented within ML and displays on the cover sheet for each procedure/policy. Electronic review documentation is performed for all procedures. If the reviewer indicates a revision is needed, this is noted as a comment. Refer to addenda C for process steps.
   b. The SOP Review checklist may be used to provide a more structured approach to SOP review, especially useful when staff participates in the review. Documentation will be retained for two years (five years for Blood Bank SOPs).
   c. Technical SOP review also includes verification of
      - LIS parameters (units of measure, reference ranges, report comments, etc.). This is accomplished by review of the test code in function MIQ and via a patient report.
      - Electronic test directory (JDOS) information

6. No handwritten changes may be made on any procedure or policy.

7. All changes require revision of entire SOP, including version change and approval. The revision history section includes revision date, a description of the change, name of the reviser and approval.

8. Draft versions are maintained in an electronic file/folder. Hard copy draft versions are labeled ‘draft’ at the top of the title page.

9. Approved draft versions of procedures may be used to train staff prior to the local effective date.

10. Changes or additions to the LIS must be considered when drafting a new or revised procedure. Refer to the procedure LIS Test Change Request for details.

11. When finalized:
    a. The effective date is added in ML. The effective date should never precede the Medical Director's approval date.
    b. Controlled copies are printed for the procedure manuals at the appropriate laboratory site(s). The location of printed SOPs is captured in ML and maintained on the Document Control Tracking form. An example is included in addenda E.
    c. The hard copy prior version is removed from the manual and discarded.
    d. The retired electronic version is automatically retired on ML on the same date as effective date of new version.

12. When procedures are discontinued, the electronic version is retired on ML and/or SmartSolve® with an appropriate explanation and maintained as archived documents. Access to archived documents is limited by security rights. The hard copy of the retired or obsolete SOP is removed from all manuals and discarded.

13. Any new SOP will be reviewed by the staff. The review documentation is included on the Training Verification form, which also covers training objectives for key elements of the process.

14. Any process revision SOP will be reviewed by the staff. Staff may read either the revised sections as listed or the entire SOP. Revision documentation may be captured on a Training Update form that is attached to the SOP or electronically via MTS. Employees are required to document their review by signature/date on the update form or completion of a quiz in MTS. SOP updates may also be presented during staff meetings/educational sessions and signed at that time.

15. Worksheets and/or forms associated with the SOP must contain a creation/revision date and are listed under Appendices or Related Documents.

16. Revisions to worksheets and forms adhere to the above document control process.

17. Refer to the specific MediaLab and SmartSolve® SOPs for detailed instructions on using the application.

6. RELATED DOCUMENTS

- SOP Format and Content
- Retention of Records and Materials
- LIS Test Change Request
- Medical Training Solutions (MTS)
- SmartSolve® (Pilgrim) EDCS: Managing New, Revised, Expire and Recurring Review of Documents
- MediaLab Basic User Functions and Information
- SOP Review Checklist – Non-Technical version (AG.F98)
- SOP Review Checklist – Technical version (AG.F99)

- Document Control Tracking form
- MIQ1 - Maintenance Inquiry, Test Code Lookup

7. REFERENCES

- College of American Pathologists, Laboratory Accreditation Manual, Laboratory General Checklist, current version.
- Standards for blood banks and transfusion services. Bethesda, MD: AABB.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP L006.004		
000	3/22/2010	Section 5: item 13 - remove email, add educational sessions Section 7: updated to current version Section 9: App C – add steps 4-6,remove first year process App D – update to job titles only	L. Barrett	C. Bowman
001	4/8/2010	Section 3: removed annual review by staff	L. Barrett	C. Bowman
002	12/20/10	Section 5: item 4 – add checklist requirement, item 14 – add MTS Section 6: update MC version SOPs Section 9: addenda A-C revised	L. Barrett	C. Bowman
003	4/7/2011	Section 3: add definition of annual review (12 months) as being within 12 months from the previous reviewed date. Section 5: add checklist requirement for new SOPs Section 9: addenda A revised, add addenda E and F	L. Barrett	C. Bowman
004	11/1/2012	Page 1: update annual review table to 'Review' Sections 2,3 & 5: update annual to 'periodic' review Section 4: add definition of periodic review Section 9: addenda C & D updated	L. Barrett	C. Bowman
005	11/20/13	Section 4: remove MasterControl terms, add SmartSolve terms Section 5: update to reflect SmartSolve application Section 6: update titles, add forms Section 9: remove forms, update A-D Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman-Gholston
6	3/3/14	Section 5 & 9: removed retention of retired hard copy SOPs	L Barrett	C Bowman-Gholston
7	4/3/14	Section 3: remove retention of retired hard copy SOPs Section 5: add tracking for SOP locations Sections 6 & 9: add Document Control Tracking form	L Barrett	C Bowman-Gholston

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Version	Date	Reason for Revision	Revised By	Approved By
8	1/19/16	Section 5: Submission of review form optional for new SOP, specify LIS and JDOS technical review process Section 6: Add MIQ Section 9: update App D (list titles without names)	L Barrett	C Bowman-Gholston
9	4/25/16	Section 5: specify electronic review if revision needed (item 5) Section 9: update App C to add review if revision is required	L Barrett	C Bowman-Gholston
10	6/14/16	Header: add WAH and GEC Section 4: add System and Site Specific SOP Section 5: add explanation of system SOP process Section 9: update App A and B	L Barrett	C Bowman-Gholston
11	3/30/18	Section 4: change recurring review email to 90 day advance notice Addendum C: specify SOP review list is 90 days before due date	L Barrett	C Bowman-Gholston
12	2/22/19	Header: update parent company Section 4: added MediaLab and associated terms Section 5: added ML transition process, change review checklist to optional Section 6: added ML SOP Section 9: updated all to match ML processes	L Barrett	C Bowman-Gholston

9. ADDENDA AND APPENDICES

A. New Procedure/Policy Process
B. Revised Procedure/Policy Process
C. Periodic (Recurring) Review Process
D. Approval Routes
E. Example of Document Control Tracking form

A. New Procedure/Policy Process

	New Procedure	Who
1.	Draft written (electronic)	Owner/supervisor
2.	Draft content reviewed by technical expert, QA, LIS	
3.	Training document written, email to QA team	Owner/supervisor
4.	Draft SOP reviewed by Medical Director	
5.	Revisions made if indicated	Owner/supervisor
6.	Final SOP emailed to Site Administrator	Owner/supervisor
7.	Load onto MediaLab (ML) and start approval process	Site Administrator
8.	SOP approved by Owner and Medical Director via ML	
9.	*Email electronic copy of approved DRAFT to Owner/supr for training*	Site Administrator
10.	Print approved DRAFT and Training document for training process	Owner/supervisor
11.	Training performed	Owner/supervisor
12.	Add effective date to implement sop (date specified by Owner/supvr)	Site Administrator
13.	Email notification sent via ML, as designated by system	N/A
14.	Controlled copies printed for appropriate manuals	QA/designee
15.	Table of Contents updated / printed	QA/designee
16.	Competency written for 6 month/annual	Owner/supervisor
17.	Training documents signed by supervisor, given to QA	Owner/supervisor
18.	Recorded on Training spreadsheet and filed	QA/designee

B. Revised Procedure/Policy Process

	Revised SOP	Who
1.	Owner requests e-copy of SOP /document	Site Administrator
2.	Revision made to existing document, revision box completed	Owner/supervisor
3.	SOP Review Checklist completed, as needed	Owner/supervisor
4.	Revision content & SOP Review Checklist reviewed by technical expert, QA, LIS	Owner/supervisor
5.	Revisions made if indicated	Owner/supervisor
6.	Training update written	Owner/supervisor
7.	Review existing training and competency documents for possible revision	Owner or QA
8.	Final SOP emailed to Document Manager	Owner/supervisor
9.	Load onto ML, and start approval process	Site Administrator
10.	SOP approved by Owner and Medical Director via ML	
11.	*Email electronic copy of approved DRAFT to Owner/supr for training*	Site Administrator
12.	Training update and approved DRAFT SOP placed in binder or onto MTS, staff notified of due date and planned implementation date. Completion of training update to be monitored by Owner/supvr	Owner/supervisor
13.	a. Add effective date to implement SOP (date specified by Owner/supvr) b. Previous version automatically retires on ML	Site Administrator
14.	Email notification sent via ML	N/A
15.	Controlled copies printed for appropriate manuals	QA/designee
16.	Previous version removed from all manuals and discarded	QA/designee

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C. Periodic (Recurring) Review Process

	BB, Field Ops and IT/LIS	Who
1.	Email notice sent via ML to document Owner for BB, Field Ops and IT/LIS	Designated reviewer
2.	Review SOP in ML, approve current version or indicate revision needed	Designated reviewer
3.	If no revision required, Print cover page and insert into manual	QA/designee
4.	**If revision required**, follow process above for **Revised SOP**	Owner/supervisor

	Core, Micro, General Lab, QA, Safety sections	Who
5.	Email a list of SOPs that are due for review each month (90 days before due date).	Site Administrator
6.	Review each listed SOP and complete SOP Review Checklist	Owner/supervisor
7.	Determine which require revision and which do not. Email that info back to Site Administrator	Owner/supervisor
8.	Launch Recurring Review in ML. If a revision is required, indicate as such	Site Administrator
9.	Review approved by Designated Reviewer via ML	Designated reviewer
10.	If no revision required, Print cover page and insert into manual	QA/designee
11.	**If revision required**, follow process above for **Revised SOP**	Owner/supervisor

D. Approval Routes

New/Revised (SOPs, Policies) Approval

Department	LEVEL 1	LEVEL 2	LEVEL 3
Blood Bank	QA Review	BB Manager Approval	Medical Director Approval
Core Lab	QA Review	Technical Manager Approval	Medical Director Approval
Microbiology	QA Review	Director of Hospital Micro Approval	Medical Director Approval
General Lab Policy, Safety	QA Review	Lab Ops Director Approval	Medical Director Approval
IT and LIS	QA Review	LIS Manager Approval	Medical Director Approval
Phleb, Processing, Customer Support	QA Review	Manager/Supervisor Approval	Medical Director Approval
Quality Assurance	QA Review	QA Specialist Approval	Medical Director Approval

New/Revised FORMS Approval

Department	LEVEL 1	LEVEL 2
Forms	Section Manager/Supervisor	Medical Director Approval

Validations Approval

Department	LEVEL 1	LEVEL 2
Validation Blood Bank	BB Manager Approval	Medical Director Approval
Validation Automated Chemistry	Technical Manager Approval	Medical Director Approval
Validation Core Lab	Technical Manager Approval	Medical Director Approval

Recurring Review

Department	LEVEL 1	LEVEL 2
Blood Bank	BB Manager Approval	Medical Director Approval
Core Lab	QA Review	Technical Manager Approval
Microbiology	QA Review	Director of Hospital Micro
General Lab Policy, Safety	QA Review	Lab Ops Director Approval
IT and LIS	LIS Manager Approval	
Phleb, Processing, Customer Support	Manager/Supervisor Approval	
Quality Assurance	QA Review	QA Specialist Approval

FORMS Recurring Review

Department	LEVEL 1
Forms	Section Manager/Supervisor

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E. Example Document Control Tracking

Procedure Name	SGAH #	printed	WAH #	printed	GEC #	printed	SGAH Manuals	WAH Manuals	GEC Manual
Computer downtime Scenarios	SGAH.LIS01.001	P	WAH.LIS01.001	P	GEC.LIS01.001	P	LIS	LIS	LIS
Critical Values-Accepting Results in LIS	SGAH.LIS03.1	P	WAH.LIS03.1	P	GEC.LIS03.1	P	LIS	LIS	LIS
Unlock Patient Files (FUNC: LOCK)	SGAH.LIS04.001	P	WAH.LIS04.001	P	GEC.LIS04.001	P	Group Lead/TIC	Group Lead/TIC	LIS
Free Lock Terminal	SGAH.LIS05.001	P	WAH.LIS05.001	P	GEC.LIS05.001	P	Group Lead/TIC	Group Lead/TIC	LIS
LOCKT Function(Lock Table Mngt)	SGAH.LIS06.001	P	WAH.LIS06.001	P	GEC.LIS06.001	P	Group Lead/TIC	Group Lead/TIC	LIS
ANIQ-Accession Number Inquiry	SGAH.LIS07.001	P	WAH.LIS07.001	P	GEC.LIS07.001	P	LIS	LIS	LIS
CRW-Credit Without Removing Results	SGAH.LIS08.001	P	WAH.LIS08.001	P	GEC.LIS08.001	P	Group Lead/TIC	Group Lead/TIC	LIS
MEM-Manual Result Entry	SGAH.LIS09.000	P	WAH.LIS09.000	P	GEC.LIS09.000	P	LIS	LIS	LIS
OEM-On Line Entry Method	SGAH.LIS10.000	P	WAH.LIS10.000	P	GEC.LIS10.000	P	LIS	LIS	LIS
AD or ADIQ	SGAH.LIS11.000	P	WAH.LIS11.000	P	GEC.LIS11.000	P	LIS	LIS	LIS
CPW-Change password	SGAH.LIS12.000	P	WAH.LIS12.000	P	GEC.LIS12.000	P	LIS	LIS	LIS
DLL-Device Lab Location	SGAH.LIS13.000	P	WAH.LIS13.000	P	GEC.LIS13.000	P	LIS	LIS	LIS
HRSND-Resend Lab Initiated Orders	SGAH.LIS14.2	P	WAH.LIS14.1	P	GEC.LIS14.2	P	Group Lead/TIC	Group Lead/TIC	LIS
I or IQ-Inquiry	SGAH.LIS15.000	P	WAH.LIS15.000	P	GEC.LIS15.000	P	LIS	LIS	LIS
IR or IRA-Interim Report	SGAH.LIS16.001	P	WAH.LIS16.001	P	GEC.LIS16.001	P	LIS, Client Service	LIS, Client Service	LIS
MIQ1-Maintenance Inquiry, Test Code Lookup	SGAH.LIS17.000	P	WAH.LIS17.000	P	GEC.LIS17.000	P	LIS	LIS	LIS
MIQ23-Maintenance Inquiry, Additional Test Information	SGAH.LIS18.000	P	WAH.LIS18.000	P	GEC.LIS18.000	P	LIS	LIS	LIS
Printers: Activation and Deactivation of Nursing Unit Printers-SGAH	SGAH.LIS19.004	P	N/A		N/A		Group Lead/TIC		
Printers: Activation and Deactivation of Nursing Unit Printers-WAH	N/A		WAH.LIS19.003	P	N/A			Group Lead/TIC	
REI - Ordering Tests, Receiving Specimens, Reprinting Labels	SGAH.LIS20.001		WAH.LIS20.001	P	GEC.LIS19.001		LIS	LIS	LIS
ACUM - Printing Archived Patient Cumulative Reports	SGAH.LIS21.001	P	WAH.LIS21.001	P	N/A		LIS	LIS	
CUM or ICUM	SGAH.LIS22.001	P	WAH.LIS22.001	P	N/A		LIS	LIS	
TR-Tracking	SGAH.LIS23.2	P	WAH.LIS23.2	P	GEC.LIS20.2	P	LIS	LIS	LIS
OFC - Cleanup Online Device File	SGAH.LIS24.000	P	WAH.LIS24.000	P	GEC.LIS21.000	P	LIS	LIS	LIS
PHYMA-Physician Maintenance	SGAH.LIS25.1	P	WAH.LIS25.1	P	GEC.LIS22.1	P	LIS	LIS	LIS
ER and ERA-Clearing Errors	SGAH.LIS26.1	P	WAH.LIS26.1	P	GEC.LIS23.1	P	Group Lead/TIC	Group Lead/TIC	LIS
REM-Requisition Entry-Modify Account #	SGAH.LIS27.000	P	WAH.LIS27.000	P	GEC.LIS24.000	P	LIS	LIS	LIS
CVIS-Verifying Specimens: Receiving, Rescheduling, Canceling	SGAH.LIS28.000	P	WAH.LIS28.000	P	N/A		LIS	LIS	
PIQ and SR-Printer Problems	SGAH.LIS29.000	P	WAH.LIS29.000	P	GEC.LIS25.000	P	LIS	LIS	LIS
QC-Outlier Report	SGAH.LIS30.000	P	WAH.LIS30.000	P	GEC.LIS26.000	P	LIS	LIS	LIS
QC OEM-Online Instruments Resulting	SGAH.LIS31.000	P	WAH.LIS31.000	P	GEC.LIS27.000	P	LIS	LIS	LIS
QC-MEM (Manual Result Entry)	SGAH.LIS32.000	P	WAH.LIS32.000	P	GEC.LIS28.000	P	LIS	LIS	LIS
QC-Updating Lot Numbers in Sunquest	SGAH.LIS33.000	P	WAH.LIS33.000	P	GEC.LIS29.000	P	LIS	LIS	LIS
QC Levy Jennings Charts	SGAH.LIS34.000	P	WAH.LIS34.000	P	GEC.LIS30.000	P	LIS	LIS	LIS
DYN-Dynamic Download for Instruments	SGAH.LIS35.000	P	WAH.LIS35.000	P	GEC.LIS31.000	P	LIS	LIS	LIS
Critical Value Report	SGAH.LIS36.1	P	WAH.LIS36.1	P	GEC.LIS32.1	P	LIS	LIS	LIS
Failed Delta Value Report	SGAH.LIS37.1	P	WAH.LIS37.1	P	GEC.LIS33.1	P	LIS	LIS	LIS
Quality Control Monthly report	SGAH.LIS38.000	P	WAH.LIS38.000	P	GEC.LIS34.000	P	LIS	LIS	LIS
PL-Core Lab Pending Logs	SGAH.LIS39.000	P	WAH.LIS39.000	P	GEC.LIS35.000	P	LIS	LIS	LIS
Delta Value-LIS Investigation	SGAH.LIS40.000	P	WAH.LIS40.000	P	GEC.LIS36.000	P	LIS	LIS	LIS