TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/5/2019
Department:	Mgmt & QA	**Due Date:**	7/31/2019
		Implementation:	**7/15/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
MediaLab Document Management   **SGMC.QA5001 v1**

Description of change(s):
This is a NEW procedure that describes MediaLab process for • new, revised and retired documents • periodic review of documents This SOP will be implemented on July 15, 2019

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

Non-Technical SOP

Title	MediaLab Document Management	
Prepared by	Leslie Barrett	Date: 6/12/2019
Owner	Cynthia Bowman-Gholston	Date: 6/12/2019

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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1. **PURPOSE**

   This procedure provides instructions to use the MediaLab (often referred to as ML) electronic document control system (EDCS) for the management of New, Revised, Retired and Periodic Review of documents.

2. **SCOPE**

   This procedure applies to all documents used within the laboratory.

3. **RESPONSIBILITY**
   - The Quality Assurance specialists and designated approvers (as delegated by the Laboratory Director) serve as document managers to create, revise and review documents.
   - The QA specialists, supervisors and managers are responsible for identifying location of copies of the policies/procedures/forms and ensuring that copies and any derivative documents are updated at the time documents are updated.
   - Supervisors and managers are responsible for communicating any changes in users and/or user permissions.

4. **DEFINITIONS**

   Controlled Copy – Printed copy of a document that 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 it 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.

5.   PROCEDURE

A. Overview

Step	Action
1	All current policies, procedures, forms and validations are kept as read-only documents in MediaLab and can only be modified or printed (controlled copy) by authorized personnel defined in the permissions section of ML.
2	All discontinued documents are removed from operations by authorized personnel using the Retired Procedure link within the ML system.
3	Retired documents in ML are kept indefinitely in a separate file.
4	Both electronic and paper copy versions of the documents are available
5	All paper copies of manuals printed from ML contain a header and footer with the current procedure/policy version number, effective date, review date and print date to ensure that both the electronic and printed versions match.
6	Changes to any document in ML automatically generates a notification to the owner of the manual, as defined in document control permissions, to reprint an updated version for incorporation into the paper manual.
7	The procedure *MediaLab Basic User Functions and Information* describes process to login, view and print documents.

B. Creating New Documents

Step	Action
1	Create the document in the appropriate format; refer to *SOP Format and Content* and/or *Document Control* procedures.
2	Go to the **Add Documents** tab Click on the link to **Upload one or more new documents**; OR, Go to the **Edit Manuals & Labels** tab Click on the parent manual and/or the sub-manual and select the link to **Upload one or more new documents into this manual**
3	Use the **Select Files** button to browse and choose the file. Multiple files can be selected.
4	Click on the link **Finish processing documents; provide title, review date, custom number and add to Document Control**. This will bring up the document or first document if multiple files were selected.
5	Click on **Preview the document** to verify it displays properly, screen shots are intact, etc. If there are errors, scroll down and click on **Remove This File, Don't Add to Document Control** button. This will remove the file. **Note**: Validation worksheets may not display properly due to Excel formatting, macros, etc. Refer to addenda A for instructions to upload separate editable and viewable copies of the file.
6	Select the a. Select the appropriate manual for the document; document number will display. A custom number may be entered if desired. b. Choose 'document type' from the drop down

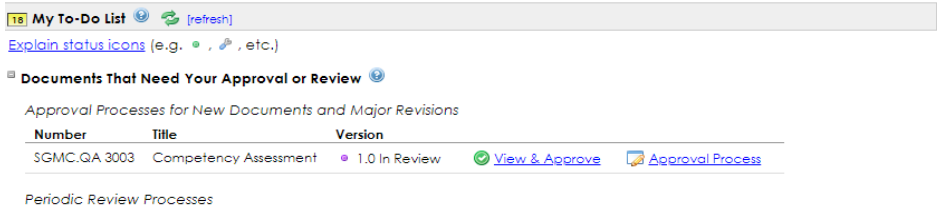| Step	Action
7	System will default to 'New document: requires approval'
8	Click on **Save changes and Add Document to Document Control** button to save the document
9	Go to section C for steps to launch document for approvals.

B. Creating Revised Documents

Step	Action
1	Access the document in the system via routine search methods. a. Click **Download For Editing** button to obtain an editable copy. b. Make necessary revisions per standard process.
2	Click on **Available actions & reports for this document** button
3	Click link for **Upload a new revision of this document** a. **Select Choose File** button and browse to find appropriate file b. System will default to Major revision (Minor revision type is NOT used) c. Add revision comments as needed. For SOPs, use 'refer to Revision History section of SOP' d. Click on **Upload Revision** button
4	System will respond with 'Major revision added.' Click the link for **Review document** to verify formatting and content display properly. If incorrect: a. Click on **Available actions & reports for this document** button b. Select link **Upload a new edit to this document** c. Correct the original document file and upload again
5	Go to section C for steps to launch document for approvals.

C. Starting Approval Process for New and Revised Documents

Step	Action
1	Approval process can be started immediately after uploading the document or at another time (if later, access the document via routine search methods).
2	Click on the link for **Start the approval process**. The approval flow displays (it is determined by pre-established customization for the manual). a. Use the link for **Request additional approvals** if needed b. The Lab Director is always the last (final) approver
3	Scroll to the Comment area. a. For new documents, this will default as Initial version – delete this b. For revised documents, key in 'refer to Revision History section of SOP' or type another appropriate comment as needed
4	Scroll to Specify an Effective Date and choose the appropriate option. Be sure to allow time for notification and/or training. **Note**: The effective date may be modified at a later time if necessary.
5	Click **Start Approval Process** button. Approvers will be notified via the Home & To-Do screen.

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D. Approving New and Revised Documents

Step	Action
1	Access your Home & To-Do page 18 **My To-Do List** 🌐 🔄 [refresh] Explain status icons (e.g. ● , 🔑 , etc.) ▫ **Documents That Need Your Approval or Review** 🌐 *Approval Processes for New Documents and Major Revisions* **Number** **Title** **Version** SGMC.QA 3003 Competency Assessment ● 1.0 In Review ✅ View & Approve 📑 Approval Process *Periodic Review Processes*
2	New / Revised documents that need your review are displayed first. Click link for **View & Approve** to begin process. The document screen will display showing: a. Comments on the version that were entered when it was uploaded b. The effective date that was chosen during upload (this can be changed) c. An optional comment box for the approver d. Button to **Approve** and a link to **Reject**

3	Scroll and review the document, then
	a. Choose the **Approve This Version** button if document is acceptable. Document will move to the next approver in the process
	b. Click link for **Reject this version** if errors are noted or other changes needed.
	  1) Enter a comment to explain the reason for rejecting. The comment will be sent to other collaborators and approvers for the document.
	  2) Edit the document and upload again.
	  3) Re-start the approval process.

4	Once a document has completed the approval process, the document administrator is notified via email. a. Training updates are created as needed. b. Documents are printed and placed into manuals on the effective date. c. For revisions, the retired document is archived on the system when the new version becomes effective and is retained indefinitely.

E. Periodic Review

Step	Action
1	Periodic review notifications begin 90 days prior to the due date (based on Lab Director approval date or last periodic review date).

2	Review may be a one or two step process as defined by the Workflow & Customizations area of ML.
	a. Blood Bank, Field Operations and IT/LIS documents are one step. Email notification is sent directly to the appropriate manager.
	b. Documents for other lab sections / departments use a 2 step process.
	  1) These require QA review first. An email notice is sent to the designated QA specialist who coordinates staff review as needed.
	  2) When the QA specialist completes the review in ML, an email is sent to the appropriate manager or director to finalize the process.

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Step	Action
3	When review is completed, ML generates a special email to the assigned QA specialist. This notice assures that printed manuals are kept up to date.
4	The QA specialists' Home & To Do page displays a notice alerting that a printed manual must be updated.
5	The QA specialists coordinate printing and updating the manual.

F. Archiving Retired Documents

Step	Action
1	The current version of a document is marked with the date superseded when a new approved version is added to the system. All retired documents in ML are archived automatically upon new revision approval and can be accessed for review by document administrators.
2	ML keeps all archived (retired) documents indefinitely.
3	To retire a document (not a revision): a. Click on **Available actions & reports for this document** button b. Select **Retire this document** c. Choose the retirement date and add an explanation in the Comment box. d. Click on **Retire This Version** button. e. Remove the document from all manuals.

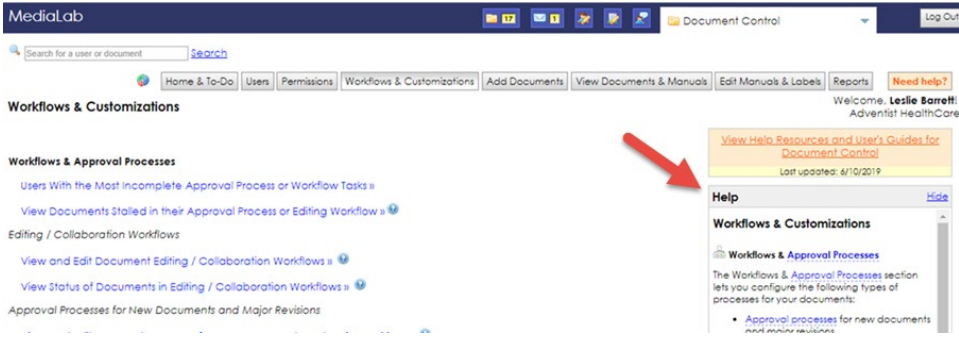## G. Other Document Actions

Step	Action
1	Forms, worksheets, work aides, etc. can be linked with their appropriate procedure or policy. a. When changing SOP or policies with linked documents, the editor is aware of all other linked material that may need to be changed including shared documents from other departments. b. Click on **Available actions & reports for this document** button c. Select **Link this document to other documents** and follow the prompts
2	Validations are stored in designated manuals for: • Blood Bank • Core Lab • Point of Care When uploading a new validation, specify the lab site at the beginning of the title or use AHC to indicate a system validation. Validations do NOT require periodic review.

H. Backup Process

Step	Action
1	Backups are zip files containing a full backup of all documents, manuals, signoffs, and all other information from the ML system. • The responsible users download this file and store it. • The users will receive a reminder e-mail once a week.

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Step	Action
2	On the Home & To-Do pages, click the link
3	Recent backups will display. Click on **Download** to access the one generated by the weekly process OR click the **Request New Backup** button.
4	The download will begin and due to the file size may take several minutes.
5	Once the download is complete, save the zip file to G:\AHC_Lab\Quality Assurance\Document Control\Media Lab backup
6	Delete the previous zip file once new one is completed.

I. Online Help

Step	Action
1	All viewing tabs (except View Documents & Manuals) display online Help on the right hand side
2	There is additional Help by selecting the **Need help?** button Click this to be directed to the MediaLab Help Center

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Step	Action
3	Select Document Control and a list of videos and job aid links will display. Explore these to get additional information or learn more on various topics, including instructions to - add and edit users - manage permissions (what users actions and access) - workflows & customizations (set up approval and periodic review)
4	There is also an online forum and a link to ask questions of MediaLab personnel.

6.   RELATED DOCUMENTS

Document Control
SOP Format and Content
MediaLab Basic User Functions and Information

7.   REFERENCES

Document Control User's Manual, Media Lab, Inc., 12/2018
MediaLab Help Center, http://www.medialab.com

8.   REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By

9.   ADDENDA AND APPENDICES

A. Providing Separate Viewable and Editable Versions of a Document

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Addenda A

Providing Separate Viewable and Editable Versions of a Document

Create a pdf file version of the document. It must correspond exactly to the content of the editable document.

Both versions will be preserved on ML and the editable file can be downloaded from ML. If the document is updated, the system will ask that both versions be replaced with revised files.

Upload the editable version as described in the SOP under 'Creating new Documents'.

To upload the pdf version:
- Under **Current Files**, select **File to display and print (PDF)**
- Click **Choose File** and select the pdf file from computer
- If necessary choose and upload an Editable file or keep the one already uploaded
- Click **Save Changes**

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