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DOCUMENT NUMBER: RL TS/DC Doc/Records - 0002
DOCUMENT TITLE: Control of Downtime Documents in MasterControl
DOCUMENT NOTES: This document is a policy statement on how to do downtime for MC using either electronic or paper

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Master Control-Downtime Plan

Purpose Provide the Kaiser Permanente SCPMG Medical Center Transfusion Services guidance on how to maintain and access critical operational documents stored in the Electronic Document Management System (EDMS) Master Control (MC) when access to the system is not available

Definitions	Critical Operational Documents	Policies, processes, procedures, and forms required to perform testing, processing, and transfusion of blood and blood components.
	Copy-Controlled	A paper or electronic document that is managed by the document control process.
	Major Document Changes	Change that affects the intent or function of a document, e.g., <ul style="list-style-type: none">• A change in regulations or policies• Adding, modifying, or deleting data or information• A change in instruments that will affect the procedure and the way the test is performed• A critical change in a test, e.g., temperature or method• Content revisions of any existing document
	Master Control	The Electronic Document Management System which contains all policies, processes, procedures, forms, job aids, and template documents for processes and activities in the Transfusion Service.
	Minor Document Changes	A change that does not affect the function or intent of the document, e.g., <ul style="list-style-type: none">• Fixing a typographical error• Adding a new reagent lot number that has been validated and will not change the procedure• Reformatting the document without changing any Information

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Policy

- All Transfusion Services must have a backup plan to access critical operational documents when Master Control system is not available to users. Some examples of when the system cannot be accessed are:
 - Widespread internet outage or slowdown
 - Master Control system failure
 - Kaiser Permanente network system downtime (internet and intranet) or critical slowdown
 - Note: Devices such as laptops, cellphones or tablets can be used to connect to the internet and access Master Control when access to the internet through the Kaiser Permanente network is not available. Use the following link:
<https://kpscal.mastercontrol.com/MasterControl/login/>
- All medical centers must have a backup system of either paper copies or local electronic access (independent of the intranet or internet).
 - It is the responsibility of the local transfusion service to maintain the backup system as described below.
- No new documents or major changes are to be implemented when access to Master Control system is not available in the region.
- Electronic Copy-Controlled critical operational documents are maintained by the Regional Blood Bank Compliance Officer or designee. These documents can be found on the Transfusion Service share drive.
- Only new and major updates to critical operational documents are required to be updated in either the paper binders or for local electronic access, as minor changes in documents do not affect the function or intent of the document.
- Staff are instructed to access Master Control and not to use the controlled-copies of critical operational documents unless Master Control is not available to users.
 - All staff are instructed on how to access controlled-copies of critical operational documents if Master Control is not available to users.

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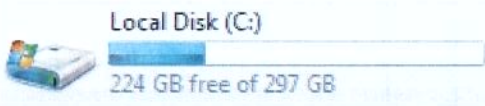
Procedure

Downtime Paper Binder	
Step	Action
1	<p>Access the Transfusion Service Share Drive to view critical operational documents.</p> <p>\\cs.msds.kp.org\scal\regs\share11</p>
2	<p>Log into Master Control and locate document required and print a controlled copy from Master Control.</p> <ul style="list-style-type: none"> Stamp document with “COPY” or “Downtime Use Only” stamp.
3	<p>File controlled copies in downtime binder accessible to staff for use when Master Control access is unavailable.</p>
4	<p>Upon effective date of new or major revised critical operational documents follow step 2 to retrieve and print document from Master Control.</p> <ul style="list-style-type: none"> Place new or revised document in binder, remove prior version of document and destroy.
5	<p>At least yearly review downtime paper binder for completeness.</p> <ul style="list-style-type: none"> Documents which have undergone biennial review or minor revisions should be printed from Master Control, stamped and placed in the binder. <ul style="list-style-type: none"> Remove prior version of document from binder and destroy.

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Procedure

Downtime Electronic File	
Step	Action
1	<p>Designate a local workstation to download the electronic critical operational documents from the Transfusion Service share drive.</p> <p>AND/OR</p> <p>Use a flash drive/CD or other removable device to download the electronic critical operational documents from the Transfusion Service share drive.</p>
2	<p>Use the following steps to download to the local drive of the designated workstation.</p> <ul style="list-style-type: none"> • From the Windows Start icon  select “Computer” • Double click the Local Disk C Drive icon <ul style="list-style-type: none"> • Hard Disk Drives (1) <div style="text-align: center;">  </div> <ul style="list-style-type: none"> • Open Users>Public>Public Desktop <p>Open the Transfusion Service Share Drive and locate the SOPs folder inside of the Master Control folder</p> <ul style="list-style-type: none"> • Right click on the SOPs folder and copy • Navigate to Public Desktop and right click to paste SOPs folder
3	<p>Use the following steps to download to a removable device.</p> <ul style="list-style-type: none"> • Insert removable device into workstation • Navigate as described in step 2 to removable device (not Local Disk C drive) • Follow instructions in step 2 to copy SOPs folder to removable device (not Public Desktop) <p>NOTE: Removable device may be encrypted by KP workstation. Have encryption key and printed instructions available for staff use and keep with removable device.</p>

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Procedure

Downtime Electronic File-continued	
4	Verify that local folder or encrypted device can be opened and critical operational documents can be viewed by another staff member.
5	Upon effective date of new or major revised critical operational documents update the electronic file from the Transfusion Service share drive. <ul style="list-style-type: none"> • The RBBCO or designee will send out a notification when the SOPs folder is updated.
6	At least yearly the Regional Blood Bank Compliance Officer or designee will review Transfusion Service share drive SOPs folder for completeness and update the critical operational documents which have undergone biennial review or minor revisions.

Non-Controlled Documents The following non-controlled documents support this procedure.

Reference
AABB Standards, current ed.
CAP Requirements, checklist, current ed.

Controlled Documents The following controlled documents support this procedure.

Reference
Document Control (Regional Quality Management Policy)
General Use of Master Control (Regional Quality Management Procedure)

Author(s) All SCPMG Transfusion Service Managers
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Reviewed and approved by:
Electronically Signed

January 14, 2013

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DOCUMENT HISTORY PAGE
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Change type: new, major, minor etc.	Changes Made to Document – Describe	Signature responsible person/Date	Med. Dir. Reviewed/ Date	Ops Dir. reviewed/ Date	Date change Imp.
New					

Master Control History of Change:		
Change type: new, major, minor etc.	Version #	Description of Change
Major	2	Updated title from <i>Control of Downtime Documents in MasterControl</i> to <i>Master Control-Downtime Plan</i> . Revised to give instruction on how to maintain critical operational documents when MasterControl access is not available.