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| **DOCUMENT NUMBER:** | SCPMG QMS - 0006 |
| **DOCUMENT TITLE:** | Document Control |
| **DOCUMENT NOTES:** | Regionwide policy for Electronic Data Management System (EDMS) |

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# Document Control

**Purpose**

This document defines the document control policy of the Southern California Permanente Medical Group (SCPMG) Laboratory Systems including the use of the MasterControl™ Electronic Document Management System (EDMS).

**Scope**

This policy is intended for all laboratories of the SCPMG Laboratory Systems. Document control requirements apply to all policies, processes, procedures, forms, job aids, and template documents for all processes and activities that are subject to accreditation.

**Definitions**

| | |
|---|---|
| Change | Any revision to an existing document |
| Collaboration | The act of soliciting input for potential changes or the establishment of an editing panel for a document |
| Copy – controlled | A paper or electronic document that is managed by the document control process |
| Copy - uncontrolled | A paper or electronic document that has not been approved for use or does not bear the appropriate document control markings as an approved current document |
| Deviation | A departure from an existing policy, process or procedure |
| Electronic Signature | A unique password associated with a specific user, in place of the traditional written signature |
| Form | A paper or electronic document (e.g., blank page or computer screen, label, or tag) that captures information and results generated as the process proceeds. A completed form becomes a record. |
| Job Aid | Instructions, lists, or quick reference materials condensed from an approved procedure that is presented in a shorter form for more rapid access to and review of the instructions |
| Major Document Changes | Change that affects the intent or function of a document, e.g.,<br>• A change in regulations or policies<br>• Adding, modifying, or deleting data or information<br>• A change in instruments that will affect the procedure and the way the test is performed<br>• A critical change in a test, e.g., temperature or method<br>• Content revisions of any existing document |

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# Document Control, Continued

**Definitions, continued**

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| Minor Document Changes | A change that does not affect the function or intent of the document, e.g.,<br>• Fixing a typographical error<br>• Adding a new reagent lot number that has been validated and will not change the procedure<br>• Reformatting the document without changing any information |
| Path of Workflow | The sequential processes in which the laboratory uses resources such as people, methods, materials, and instruments to transform a clinician's order into the laboratory information captured in the report of results for patient management, including preexamination, examination and postexamination processes<br>• **Preexamination processes** include include all activities from the time the laboratory examinations are ordered through the time that the samples are processed and delivered to the testing locations or, for referred testing, transported to outside laboratories. For surgical pathology and cytology, preexamination activities extend from the time the tissue or sample is removed or collected from the patient to the point at which the slides are prepared, stained, and ready for diagnostic assessment and interpretation. Preexamination activities may also include the laboratory's provision of consultations and/or advice given about selecting examinations.<br>• **Examination processes** include the activities of performing the testing, which often involve operating an automated analytical instrument and verifying the results; interpreting the results or findings, which may include a physician's evaluation; and recording the results, in either or both written or electronic formats. In the anatomic pathology specialties, examination includes the diagnostic assessment of the samples and/or slides, peer consultation, and recording the findings.<br>• **Postexamination processes** include activities related to reporting results, including any critical or alert values, as well as archiving results and sample material. |

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# Document Control, Continued

**Definitions, continued**

| | |
|---|---|
| Policy | A set of basic principles or guidelines that direct or restrict the organization's (or laboratory's) plans, actions, and decisions - the "what is done and why." |
| Process | A set of interrelated or interacting activities that produce a product or service—the "how it happens." A process may be documented as a flow chart or table that describes operations in the laboratory's path of workflow or activities within a quality system essential. |
| Procedure | A set of instructions that describe the stepwise actions taken to complete activities identified in processes —the "how to do it." Procedures transform the intent described in the policies into action. There is at least one procedure for each activity in a process. |
| Record | • (noun) evidence of results achieved or activities performed<br>• (verb) the action of documenting activities performed or results achieved |
| Template | Pre-developed page layout in electronic or paper media used to make new pages with a similar design, pattern, style, or content |
| Variance | Approval to deviate from the performance or part of the performance of the document as written |

**Policy**

- The MasterControl™ EDMS is the approved system for use within the SCPMG Laboratory Systems. Exceptions may be approved locally.
- Only currently authorized versions of appropriate documents will be available for active use at relevant locations.
- Personnel are required to read the policies/procedures relevant to their job activities.
- Documents are periodically reviewed, revised when necessary, and approved by authorized personnel.
- Invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use. Retained or archived superseded documents are appropriately identified to prevent their inadvertent use.
- Approved procedures describe how changes to documents maintained manually and in the EDMS are made and controlled.
- Each electronic signature is unique to one individual and cannot be borrowed or lent, reused by, or reassigned to, anyone else.
- Documents should not be shared outside the organization without the approval of the CLIA Laboratory Director or the applicable Physician in Charge.

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# Document Control, Continued

**Document Format**

- New documents should be written in approved formats.
- Existing documents should be converted to the approved formats within a 2 year time period.
- Templates are provided in the approved format for Policy, Process, Procedure, and selected Forms.
- Documents are uniquely identified to include title, document number, version/revision number, number of pages, authority for issue, and source identification.

**Review**

- Documents and forms must be reviewed by the current CLIA Laboratory Director or designee at least biennially (every two years).
  - The CLIA Laboratory Director can delegate to Laboratory Managers or Operations Directors to serve as designees for this review.
  - The CLIA Laboratory Director shall designate in writing the individual authorized to perform and document the review. This authorization could be in the form of specifying a knowledgeable person or job category.
  - Reviews are considered to be timely if they are completed within two years plus 30 days of the last review date.
- Documents must be complete and current. If a document has changed, or is new, the CLIA Laboratory Director must review the document.
  - Current practice must match policy and procedure documents.
  - Document reviews are captured in the electronic document management system.
- If there is a change in CLIA directorship, the new CLIA Laboratory Director must ensure, over a reasonable period of time, that laboratory documents are current and have been appropriately reviewed.

**Approval**

- The CLIA Laboratory Director (not a designee) shall review and approve new documents before implementation.
- Documents with major changes to an existing document should be approved in the same manner as a new document.
- Electronic publication of a document should be delayed after its final approval, if necessary, to coincide with the implementation of practice in the laboratory and to allow any training and competence assessment of the affected staff to be completed.

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# Document Control, Continued

**Change Control**

- Change control is initiated by the change request process described in the procedure: *Revising a Document in MasterControl.*
- Staff should notify the immediate supervisor or team leader when a change to a document is needed.
- Minor changes should be held until the next review or major change.
- When changes to a particular document are made, the document change initiator should determine whether any other documents or processes will be affected. This assessment should be recorded.
- Non-controlled document references should be verified for applicability and updated during the periodic review of the document.
- Amendment of a document by hand pending the reissue of a document is discouraged, but is permissible under the following circumstances:
  - The change is a critical one that affects the comprehension or performance of a procedure that impacts patient care, or the safety, potency, or purity of a blood product.
  - The change is needed quickly to respond to a compliance issue or a change with a required timeline.
  - **And** the document owner is authorized to make critical changes manually by the CLIA Laboratory Director of the site(s) impacted by the change.
    - The amendment(s) must be clearly marked, initialed, and dated by the document owner.
    - The change must be initiated in the EDMS within 24 hours.
- If the CLIA Laboratory Director of the site impacted by the change is not immediately available, the document owner must immediately notify the CLIA Laboratory Director in writing. E-mail is acceptable documentation of notification of the CLIA Laboratory Director.

**Controlled Copies**

- The controlled copy (paper or electronic) is a copy of a document maintained in the EDMS and used in the event of a downtime, which has been generated by an authorized person and is of the same validity as the copy in the EDMS.
- Printed documents from the EDMS have an expiration date of 24 hours.
- Electronic copies of published documents saved outside of MasterControl become inaccessible after the expiration date, making it no longer viewable.
- Printed controlled copies should not be photocopied, written on, or have correction fluid applied to them.

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# Document Control, Continued

**Archive**

- Paper documents in procedure manuals, previously approved and signed by the CLIA Laboratory Director and Operations Director are the archived documents of the SCPMG laboratory until they reach their retirement date.
- Paper documents contain original signatures, annual review dates, initials and revision notes. Subsequent documentation of procedure history, including review and approvals of the initial upload will be in the electronic document management system.
- When a procedure is discontinued, an electronic copy is maintained for at least 10 years as long as the EDMS is capable.
  - Documents archived prior to going live on the EDMS are archived and maintained for the appropriate time as specified below. Records of the initial date of use and retirement date are on the archived documents.
    - In the general laboratory, procedures must be maintained a minimum of 3 years after discontinuation.
    - In transfusion medicine, Refer to RL Transfusion Service/Donor Center Policy: *Records: Storage, Maintenance and Retention of Transfusion Service and Donor Center Records*
    - For genetic testing, it is recommended to meet the requirements of some states relating to the testing of minors (under the age of 21); laboratories should retain procedures (paper or electronic) for at least 23 years (to cover the interval from the fetal period to age 21).

**Downtime/ Backup**

- Documents are maintained on a secure server hosted by the EDMS vendor and are available via the internet.
- Controlled copies of selected documents can be used in the event of downtime.

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# Document Control, Continued

**Variances**

- When a compelling reason requires a deliberate, planned deviation from an existing policy, process or procedure, that situation must have documentation that:
  - Describes the compelling reason or situation requiring the deviation.
  - Documents the approval of the CLIA Laboratory Director (or their Pathologist/PhD designee) prior to performing the deviation. This could be a signature or documentation of a phone call or electronic communication with the approver.
  - If documentation of CLIA Laboratory Director/Pathologist approval is obtained by a phone call or other electronic method, then identification of the person obtaining that approval, and the date and time of the approval must be documented.
- Distribution
  - For variances to SCPMG standardized regional procedures, send the request to Regional Quality within a reasonable time, not to exceed one week.
  - For variances to Transfusion Services and Donor Center procedures, send the deviation form to Transfusion Medicine.
  - For variances to local Medical Center area procedures, notify via the Medical Center laboratory quality structure as applicable.
- When the compelling reason is one that will permanently disallow the performance or part of the performance of the document as written,
  - Submit the request to Quality Subcommittee of Laboratory Operations for approval.
  - If approved, it is presented to the Laboratory Operations Committee for approval.
- All variances are subject to biennial review by the Quality Subcommittee of Laboratory Operations.

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# Document Control, Continued

**EDMS Roles**

| Role Name | Task | Responsibilities |
|---|---|---|
| View Only | General Staff | • Views documents, and<br>• prints copies. |
| Creator/Reviser | • Lead Staff<br>• Lab Managers<br>• Subject Matter Experts<br>• Assistant Directors<br>• Section Managers<br>• Operations Directors (as applicable) | • Creates a new document,<br>• launches a document on a route,<br>• collaborates,<br>• approves collaboration,<br>• revises documents,<br>• performs periodic reviews,<br>• views documents, and<br>• trains and assesses competency of View Only users on the EDMS. |
| Reader | • Operations Director<br>• CLIA Director (MD)<br>• Technical Director | • Approves documents,<br>• collaborates,<br>• performs periodic reviews, and<br>• views documents. |
| Sub administrator | Persons trained in the build and management of the EDMS | • Manages the build of the local vaults,<br>• resets passwords locally,<br>• adds/inactivates users<br>• trains and assesses competency of Creator/Revisers and Readers on the EDMS, and<br>• monitors timeliness of document processes. |
| Administrator | Individual controlling the licensing of the EDMS | • Performs final signoff on substantive changes in the build, and<br>• monitors license usage. |

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# Document Control, Continued

**Non-Controlled Documents**

The following non-controlled documents support this policy.

- ISO 15189E 2007 2nd edition
- 42 CFR 493.1251 - Standard: Procedure Manual
- 42 CFR 493.1105 - Standard: Retention Requirements
- CLSI GP26-A4 Quality Management System: A Model for Laboratory Services, 2011
- CLSI GP2-A5 Laboratory Documents: Development and Control, Approved Guideline – Fifth Edition, 2006
- CAP Laboratory General Checklist, All Common Checklist
- Carson, TH. Ed, 27th ed. Standards for Blood Banks and Transfusion Services, American Association of Blood Banks, 2011 (Std. 1.3.2)

**Controlled Documents**

The following controlled documents support this policy.

| Procedure |
|---|
| General Use of MasterControl |
| Creating a New Document InfoCard in MasterControl |
| Collaborating in MasterControl |
| Approving and Implementing Documents in MasterControl |
| Revising a Document in MasterControl |
| Reviewing and Archiving Documents in MasterControl |
| **Form** |
| Policy Template |
| Process Template |
| Procedure Template |

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